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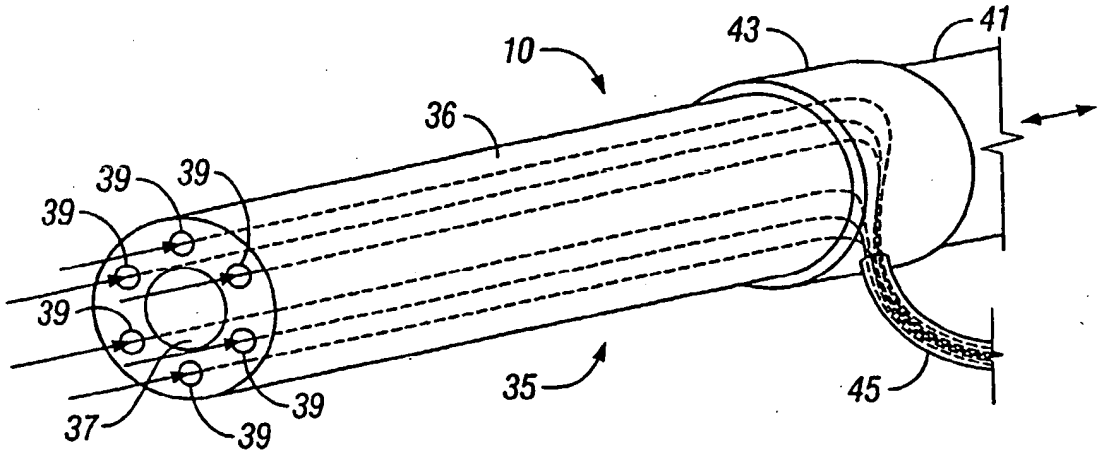
(54) Title: METHODS AND APPARATUS FOR ENDOSCOPIC CARDIAC SURGERY



(57) Abstract: Apparatus and surgical methods establish temporary suction attachment to a target site on the surface of a bodily organ for enhancing accurate placement of a surgical instrument maintained in alignment with the suction attachment (17). A suction port (19) on the distal end of a supporting cannula (10) provides suction attachment to facilitate accurate positioning of a needle (21) for injection penetration of tissue at the target site on the moving surface of a beating heart. Force applied via the suction attachment (17) to the surface of the heart promotes perpendicular orientation of the surface of the myocardium for enhanced accuracy of placement of a surgical instrument thereon.

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METHODS AND APPARATUS FOR ENDOSCOPIC CARDIAC SURGERY

Field of the Invention:

[0001] This invention relates to endoscopic cardiovascular surgical procedures and instruments, and more particularly to apparatus including a vacuum-assisted cannula and surgical instruments operable therewith, and to surgical procedures utilizing such apparatus.

Background of the Invention:

[0002] The injection of undifferentiated satellite cells or myocytes or stem cells into the myocardium of a beating heart in the endoscopic procedure of cellular cardiomyoplasty must be performed carefully to avoid complications. A specialized instrument, as described in the aforecited applications, is advanced through an operating channel of an endoscopic cannula to deliver cells in controlled manner into a beating heart. If a needle is used to inject the cells, sufficient control must be provided to ensure that the needle does not puncture a coronary vein or artery and cause hemorrhage within the pericardial space, with subsequent cardiac tamponade. Movement of the beating heart further complicates needle placement because of erratic movement of the coronary vessels as needle insertion is attempted. Similarly, placement of other elements such as epicardial pacing or defibrillation leads into the myocardium of a beating heart must be carefully placed to avoid puncture of a coronary vein or artery with concomitant complications.

Summary of the Invention:

[0003] In accordance with the illustrated embodiments of the present invention, a substantially rigid cannula includes separate elongated lumens

extending between distal and proximal ends of the cannula to provide an instrument channel and one or more separate vacuum channels that terminate in a suction port located adjacent the distal end of the cannula. The instrument channel is sized to accommodate various surgical instruments including a hollow needle for penetrating the myocardium to deliver the cells. The needle is configured for shallow penetration to avoid puncturing into a chamber of the heart with associated complications. In an alternative embodiment, an instrument channel carried by a 'needle' is sized to accommodate epicardial pacing or defibrillating leads. Additionally, the cannula with separate lumens or channels therethrough may be in incorporated with or disposed within an instrument channel of an endoscopic cannula that houses an endoscope aligned with a distal transparent tip. This assemblage of surgical instruments may be conveniently positioned through tissue disposed between a subxiphoid incision and a surgical site on the epicardium of a beating heart, or positioned through tissue disposed between a thoracotomy incision and a surgical site on the epicardium of a beating heart. In some cases, a laterally expandable sheath may be employed to form a working cavity in tissue to facilitate the placement of the vacuum port and associated instrument channel at the surgical site on the epicardium.

Brief Description of the Drawings:

[0004] Figure 1 is a side view of a vacuum-assisted injection cannula in accordance with one embodiment of the present invention;

[0005] Figure 2 is a side view of an endoscopic cannula for use with the injection cannula of Figure 1;

[0006] Figure 3 is a partial side view of the assembled cannulas of Figures 1 and 2 in a surgical procedure;

[0007] Figure 4a is a partial side view of a split needle according to one embodiment of the present invention;

[0008] Figure 4b is a partial side view of a needle with short bevel sharpened tip according to an embodiment of the present invention;

[0009] Figure 5 is a perspective view of another embodiment of an injection cannula in accordance with the present invention;

[0010] Figures 6a and 6b comprise a flow chart illustrating a surgical procedure in accordance with the present invention;

[0011] Figure 7 is a plan view of an epicardial lead with screw-like distal tip and attached proximal connector;

[0012] Figure 8 is a partial plan view of a needle in one configuration incorporating an open instrument channel for placement of an epicardial lead;

[0013] Figure 9 is a partial plan view of the needle of Figure 8 in a complementary configuration incorporating a closed instrument channel; and

[0014] Figure 10 is a plan view of a cannula with attached instrument channel.

Detailed Description of the Invention:

[0015] Referring now to Figure 1, there is shown one embodiment of a suction assisted insertion cannula 10 according to the present invention including a closed channel 9 and a superior channel 11 attached to the closed channel. The closed channel 9 includes a suitable hose connection 13 and a three-way vacuum control valve 15 including an irrigation port 16 at the proximal end, and a suction pod 17 positioned on the distal end. The suction pod 17 includes a porous distal face or suction ports 19 that serves as a vacuum port which can be positioned against the epicardium to facilitate temporary fixation thereto as a result of the reduced air pressure of vacuum supplied to the suction pod 17. The distal end of the superior instrument

channel 11 that is attached to the closed channel 9 may thus be held in accurate fixation in alignment with a selected surgical site on the epicardium relative to the suction fixation location of the suction pod 17 on the epicardium. A rounded smooth surface of suction pod 17 may be used to apply gentle pressure on the epicardium to stop bleeding at small puncture sites, or to allow injected cells to be absorbed without exiting back out of the injection.

[0016] The superior channel 11 is sized to accommodate slidable movement therein of a hollow needle 21 that may exhibit lateral flexibility over its length from the needle hub 23 at the proximal end to the sharpened distal end 25. When used to inject cells, the needle 21 may be about 22-25 gauge in diameter and includes an internal bore of sufficient size to facilitate injection of cells without incurring cell damage, or lysis. When used to place pacing or defibrillating leads, the needle 21 may be about 2-2.5 mm in diameter with an internal bore of sufficient size to accommodate a lead of diameter up to approximately 2 mm in diameter.

[0017] Due to the relatively large diameter of the needle for epicardial lead placement (approximately 2-2.5 mm in diameter), a solid obturator 20 may optionally be used with the slotted needle 21, as illustrated in Figure 4a, for insertion into the myocardium. The obturator 20 closes off the distal end of the needle, to prevent the needle from coring out a section of the myocardium during needle insertion, with associated excessive bleeding. The obturator 20 may be removed from the needle 21 after needle insertion and the epicardial lead advanced into the myocardium. The epicardial lead, as illustrated in Figure 7, is flexible and may be positioned within its own split sheath or tube for easier insertion through the slotted needle.

[0018] After the lead is implanted in the heart by the procedure described above, the proximal end is disposed out through the small initial incision in the patient. The proximal end may then be tunneled subcutaneously from the

initial incision to an incision in the patient's upper chest where a pacemaker or defibrillator will be located. A small, elongated clamp is passed through the subcutaneous tunnel to grasp the proximal end of the epicardial lead to facilitate pulling the lead through the tunnel for placement and attachment to the pacemaker or defibrillator.

[0019] Both the superior channel 11 and the needle 21 may be longitudinally slotted for placing an epicardial lead that may incorporate a large diameter connector, as illustrated in Figure 7. A split sheath can be used around the lead to facilitate advancement and rotation of the lead via the slotted needle. After anchoring such lead in the myocardium, for example by screwing in the distal tip, the slotted needle 21 is rotated to align its slot with the slot in the superior channel 11, thus allowing the lead to be released from the cannula.

[0020] The structure according to this embodiment of the invention, as illustrated in Figure 1, is disposed to slide within the instrument channel in an endoscopic cannula 27, as shown in Figure 2. This cannula includes an endoscope 29 therein that extends from a tapered transparent tip 31 attached to the distal end, to a viewing port 33 at the proximal end that can be adapted to accommodate a video camera. In this configuration, the structure as illustrated in Figure 1 may be positioned within the instrument channel in the cannula 27 of Figure 2 to position the suction pod 17 and sharpened needle tip 25 in alignment with a surgical target on the heart, as illustrated in Figure 3. The suction pod 17 is temporarily affixed to the epicardium in response to suction applied to the porous face 19 of the suction pod 17 under control of a suction valve 15, and the sharpened tip 25 of the needle 21 may then be advanced to penetrate into the myocardium at an accurately-positioned surgical site, all within the visual field of the endoscope 29 through the transparent tip 31. Following injection, the needle is withdrawn and the suction pod 17 may be

rotated or otherwise manipulated to position a surface thereof on the injection site with gentle pressure to allow time for the injected cells to be absorbed and to control any bleeding occurring out of the injection site.

[0021] As illustrated in Figures 2 and 3, the various channels in the endoscopic cannula 27 and the insertion cannula 10 have specific orientations with respect to each other in order to provide stabilization of the epicardial surface and allow visual control of the injection process. In the endoscopic cannula 27, the instrument channel is positioned below the endoscopic channel and this allows the cannula 27 and the transparent tapered tip 31 on the endoscope 29 to retract the pericardium away from the epicardial surface of the heart at the operative site. This creates a space 95 for contacting the heart below the pericardium, as illustrated in Figure 3. As the cell insertion cannula 9 is advanced forward out of the instrument channel of the endoscopic cannula 27, the suction pod 17 is visualized through the endoscope 29 and transparent tip 31, as the suction pod 17 is placed on the epicardial surface of the heart. At a selected site on the heart, for example, at the site of an old myocardial infarct, the suction is activated to attach the pod 17 to the heart. The configuration of the instrument channel of the cell insertion cannula 10 on top of the suction channel 9 allows the needle 21 to be visible as soon as it exits from the instrument channel, and remain visible within the visual field of the endoscope along the entire path of travel of the needle 21 from the insertion cannula 10 to its insertion into the myocardium. Continuous visualization of the needle 21 in this manner helps to prevent inadvertent puncture of a coronary vessel.

[0022] The configuration of the suction pod 17 and the needle 21 on the insertion cannula 10 also facilitates delivery of substances or devices in an orientation perpendicular to the epicardial surface. For placement of pacing or defibrillation leads, it is particularly desirable to have the leads enter the

myocardium in an orientation that is generally perpendicular to the epicardial surface for secure anchoring in the myocardium. Generally, the insertion cannula 10 is advanced through the endoscopic cannula 27 and approaches the epicardial surface of the heart at a tangential angle. Accordingly, the insertion cannula 10 is configured to facilitate deforming the epicardial surface in order to achieve perpendicular entry of the needle 21 into the myocardium, as illustrated in Figure 3. The suction pod 17 of the insertion cannula 10 temporarily attaches to the epicardial surface upon application of vacuum under control of the valve 15. Downward pressure can be exerted on the epicardial surface via the substantially rigid insertion cannula 10. The pliable myocardium thus deforms to create a surface ledge 100 distal to the suction pod 17 oriented perpendicular to the axis of the superior instrument channel 11 of the insertion cannula 10, as illustrated in Figure 3. As the needle 21 is advanced, it enters the myocardium generally perpendicularly to the epicardial surface as thus deformed for desirable lead placement or cell injection.

[0023] Referring now to Figures 3 and 4b, it should be noted that the insertion cannula 10 is sized to fit in slidable orientation within the working channel of about 5-7 mm diameter in the endoscopic cannula 27. The outer dimensions of the suction pod 17 are less than 5-7 mm diameter and is configured on the distal end of the closed channel 9 not to obstruct the forward movement of the needle 21 past the closed, back surface 19 of the suction pod 17.

[0024] As illustrated in Figure 4b, the sharpened distal end 25 of the needle 21 includes a relatively short, sharpened bevel of length approximately 2-3 times the diameter of the needle. The short bevel length of the needle assures that cells are injected within the myocardium, and that part of the needle bevel does not extend into a heart chamber, with resultant intracardiac cell delivery. A visual and tactile marker 30 of extended diameter may be

incorporated into the distal portion of the needle 21. As the needle is advanced into the myocardium, the marker 30 of enlarged diameter offers increased resistance to tissue insertion. The marker 30 is positioned just proximal to the bevel of the needle and extends proximally a distance of approximately 5-7 mm.

[0025] A needle stop may also be built into the proximal end of the needle 21. Such a stop may simply be the hub 23 of the needle, and the needle 21 may be sufficiently limited in length that only a specific length of needle, for example 1 cm, may extend out of the instrument channel of the cell insertion cannula 10 when the needle hub 23 abuts against the proximal face of the instrument channel 11. However, the distal visual and tactile marker 30 provides generally more precise guide to depth of needle penetration under conditions of different angles of possible needle insertion with respect to the epicardial surface. With an extremely shallow angle of entry, a needle of short length may not enter the heart at all. In use, the transparent tip 31 and the suction pod 17 of the assembled cell injection device may be manipulated to reshape a localized portion of the epicardial surface of the heart to allow perpendicular entry of the needle into the myocardium, as illustrated in Figure 3. With the suction pod 17 activated, gentle manipulation of the insertion cannula allows adjustment of the needle entry angle while maintaining temporary vacuum-assisted attachment to the epicardial surface, as shown in Figure 3.

[0026] The insertion device may also inject substances other than cells. Angiogenic agents such as vascular endothelial growth factor (VEGF) may be injected into myocardial scar tissue in an attempt to stimulate neovascularization, or growth of new blood vessels into the area. Insertion of the needle itself into myocardial tissue may be therapeutic as a form of transmyocardial revascularization (TMR). It is believed that needle insertion

injury may stimulate angiogenesis, or growth of new vessels into a devascularized portion of the heart. The cell insertion cannula thus promotes accurate placement of a needle 21 into myocardium under continuous visualization. When combined with the endoscopic cannula, the needle placement may be accomplished through a small, 2 cm subxiphoid skin incision.

[0027] The illustrated embodiment of the insertion cannula includes a substantially rigid cannula containing a closed channel 9 ending in a distal suction pod 17, and a superior instrument channel 11 ending immediately proximal to the suction pod 17 on the closed channel 9. In operation, a long needle is advanced through the instrument channel 11. The needle 21 contains a marker 30 immediately proximal to its beveled tip 25 that serves as a visual or other sensory indicator of the depth of needle insertion. The marker 30 may be a segment of expanded diameter to provide tactile feedback upon insertion into myocardial tissue. For example, a gold-colored metallic sleeve 30 may be welded or soldered onto the needle 21 to provide both visual and tactile feedback of the depth of penetration of the needle tip into the myocardium. The marker may alternatively include a series of rings etched in the needle or a band etched or sandblasted in the same area. A three-way valve 15 on the cannula 9 allows suction in the pod 17 to be turned on or off, and allows irrigation fluid such as saline to be injected through the suction pod 17 while suction is turned off.

[0028] Referring now to Figure 5, there is shown a perspective view of another embodiment of an insertion cannula 35 similar to insertion cannula 10 described above, including an elongated body 36 having a central bore 37 therethrough to serve as an instrument channel, and including one or more eccentric channels 39 that serve as suction conduits. The central bore may be sized to slidably support surgical instruments 41 therein such as tissue cutters

and dissectors, electrocoagulators, injection needles, and the like. For example, surgical instrument 41 may be an energy-supplying ablation probe for epicardial ablation of myocardial tissue in the treatment of cardiac arrhythmia such as atrial flutter or atrial fibrillation. The ablation probe 41 may use radio frequency, microwave energy, optical laser energy, ultrasonic energy, or the like, to ablate myocardial tissue for arrhythmia correction. The suction pod 17 attaches to the epicardial surface while suction is turned on at valve 15 to facilitate advancing the ablation probe 41 through the cannula 35 into contact with the heart at the desired site under direct endoscopic visualization for precise myocardial ablation.

[0029] The left atrial appendage is frequently the site or source of thromboemboli (blood clots) that break away from the interior of the left atrial appendage and cause a stroke or other impairment of a patient. An ablation probe 41 can be used in the cannula 35 to shrink and close off the appendage to prevent thromboemboli from escaping.

[0030] In a similar procedure, a suture loop or clip can be placed through the cannula 35 and applied tightly around the atrial appendage to choke off the appendage.

[0031] The suction channels 39 in the cannula 35 of Figure 5 may form a suction attachment surface at the distal end of the cannula 35, or may be disposed in fluid communication with a suitable suction pod with a porous distal face and with a central opening in alignment with the central bore 37. The suction-attaching distal face provides an opposite reaction force against a tool that exerts a pushing force such as a needle, screw-in lead tip, or other device deployed through the central bore 37 of the cannula 35. The proximal ends of the eccentric channels 39 are connected via a manifold or fluid-coupling collar 43 to a vacuum line 45. Alternatively, a single channel 39 may communicate with an annular recess or groove disposed concentrically about

the central bore 37 within the distal end to serve as a suction-assisted attachment surface.

[0032] In this configuration, an injection needle 21 slidably disposed within the central bore 37 may be extended beyond the distal end of the cannula 35, within the visual field of an endoscope, in order to orient the needle in alignment with a surgical target site on the pericardium prior to positioning the distal end of the cannula on the pericardium and supplying suction thereto to temporarily affix the cannula 35 in such position. A cannula 35 formed of transparent bioinert material such as polycarbonate polymer facilitates visual alignment of the cannula 35 and the central bore 37 thereof with a surgical site, without requiring initial extension of a surgical instrument, such as a cell-injection needle, forward of the distal end within the visual field of an endoscope. In an alternative embodiment, the central lumen or bore 37 may serve as a suction lumen with multiple injection needles disposed in the outer lumens 39.

[0033] Referring now to the flow chart of Figures 6a, 6b, the surgical procedure for treating the beating heart of a patient in accordance with one embodiment of the present invention proceeds from forming 51 an initial incision at a subxiphoid location on the patient. The incision is extended 52 through the midline fibrous layer (linea alba). The tissue disposed between the location of subxiphoid incision and the heart is bluntly dissected 53, for example, using a blunt-tip dissector disposed within a split-sheath cannula of the type described in the aforecited patent application. The channel thus formed in dissected tissue may optionally be expanded 55 by dilating tissue surrounding the channel, for example, using a balloon dilator or the split-sheath cannula referenced above, in order to form a working cavity through the dissected and dilated tissue, although this may be unnecessary.

[0034] An endoscopic cannula, for example, as illustrated in Figure 2 including an endoscope and a lumen for receiving surgical instruments therein is inserted 57 into the working cavity through the subxiphoid incision toward the heart to provide a field of vision around a target site on the heart, and to provide convenient access via the lumen for surgical instruments of types associated with surgical procedures on the heart. The first such instrument is the pericardial entry instrument, as described in the aforementioned provisional applications, which generally grasp the pericardium in a side-bite manner to form an elevated ridge of tissue through which a hole can be safely formed without contacting the epicardial surface. Once the pericardium is penetrated 58, other instruments can be inserted through the hole and into the working space 58. One such instrument is an insertion cannula, for example, as illustrated in Figure 1, that includes a suction channel and an instrument channel and is slidably supported 59 within the instrument lumen of the endoscopic cannula. The suction channel of such instrument extends through the length thereof from a proximal end to a suction pod at the distal end that can be extended into contact 61 with the beating heart of the patient at a selected target site. The suction pod can be carefully positioned on the pericardium under visualization through the endoscope, and the suction can be applied to establish temporary attachment of the injection cannula to the pericardium. A needle or other surgical instrument such as surgical scissors or an electrocauterizer, or the like, is then moved into contact 63 with the pericardium to perform a surgical procedure at or near the target site. One surgical procedure includes penetrating the pericardium and myocardial tissue with the needle, typically in a region of a previous infarct, to stimulate transmyocardial revascularization or to inject undifferentiated satellite cells to promote regrowth of scarred myocardial tissue. During such surgical procedure, it is important to limit the depth of penetration of the needle in

order to assure injection penetration only into the myocardium, and to avoid puncture into a heart chamber. A penetration indicator 30 may be disposed about the needle near the distal end thereof to provide visual and/or tactile feedback as mechanisms for limiting 65 the depth of needle penetration, as illustrated in Figure 4b. Specifically, visualization of the penetration indicator via the endoscope facilitates control of manual extension of the needle into the myocardium. Additionally, an indicator of increased diameter disposed about the needle at an appropriate position proximal the distal end serves as a penetration indicator by providing increased tactile feedback of limiter by increasing the resistance to insertion of the needle into the myocardium. After needle penetration and cell injection, the suction pod 17 may be manipulated to apply gentle pressure 66 at a surface thereof to the injection site to allow cell absorption and to tamponade any bleeding from the injection site.

[0035] After one or more injections of the myocardium, positioned and performed as described above, the injection cannula and the needle supported therein are removed 67 through the instrument lumen of the endoscopic cannula which is then also retrieved 69 from the working cavity, and the initial subxiphoid entry incision is then sutured closed 71 to conclude the surgical procedure.

[0036] The endoscopic cannula and pericardial entry instrument may also be applied from a thoracotomy incision to gain access to the heart. A 2 cm incision is performed in an intercostal space in either the left or the right chest. Ideally, the incision is made between the midclavicular line and the anterior to mid axillary line. The incision is extended through the intercostal muscles and the pleura, until the pleural cavity is entered. The endoscopic cannula is then inserted into the pleural cavity and advanced to the desired area of entry on the contour of the heart, visualized within the pleural cavity. The pericardial entry instrument and procedure as described in the aforementioned applications are

used to grasp the pleura, and a concentric tubular blade cuts a hole in the pleura, exposing the pericardium underneath. The pericardium is then grasped by the pericardial entry instrument, and the tubular blade is used to cut a hole in the pericardium, allowing access to the heart. The transparent tapered tip 31 of the endoscopic cannula 29 aids in pleural and pericardial entry by retracting lung and pleural tissue that may impede visualization of the pericardial entry site. Once the pericardium is entered, the endoscopic cannula 29 may be moved around to visualize anterior and posterior epicardial surfaces.

[0037] Therefore the surgical apparatus and methods of the present invention provide careful placement of an injection needle or other surgical instrument on the surface of a beating heart by temporarily affixing the distal end of a guiding cannula at a selected position on the heart in response to suction applied to a suction port at the distal end. The guiding cannula can be positioned through a working cavity formed in tissue between the heart and a subxiphoid or other entry incision to minimize trauma and greatly facilitate surgical treatment of a beating heart. Such treatments and procedures may include needle punctures of the myocardium, or injections therein of undifferentiated satellite cells, or other materials, to promote vascularization or tissue reconstruction, for example, at the site of a previous infarct. Such treatments and procedures may also include placing of pacing or defibrillating leads into the myocardium. Such treatments and procedures may further include positioning and manipulation of an ablation probe to ablate myocardial tissue and correct cardiac arrhythmias.

What is claimed is:

1. Apparatus for performing a surgical procedure on the heart of a patient under visualization through an endoscope, the apparatus comprising:

a first cannula including an instrument channel disposed between proximal and distal ends thereof and including a lumen for slidably receiving an endoscope therein to provide a visual field forward of the distal end;

a second cannula slidably positionable within the instrument channel of the first cannula, with a channel of the second cannula extending between distal and proximal ends thereof; and

a lumen in the second cannula communicating with a suction port positioned near the distal end of the second cannula for contacting a target site on the heart, the channel of the second cannula slidably receiving therein an instrument for extending beyond the distal end of the second cannula into contact with the heart within the visual field of the endoscope.

2. The apparatus according to claim 1 in which the first cannula is configured for establishing a working cavity through tissue between the heart and a subxiphoid entry location.

3. The apparatus according to claim 1 in which the instrument includes a needle for passing through the channel of the second cannula to extend from the distal end of the second cannula to penetrate the heart to a selected depth.

4. The apparatus according to claim 3 in which the needle includes a bore therethrough and includes a sharpened distal end for penetrating the heart to the selected depth to inject a substance therein.

5. The apparatus according to claim 4 in which the needle is configured to penetrate the myocardium of the heart to inject therein undifferentiated satellite cells, myocytes, or stem cells.

6. The apparatus according to claim 3 in which the needle is configured to penetrate the myocardium of the heart to place therein a conductive lead for electrical pacing or defibrillation of the heart.

7. The apparatus according to claim 6 in which the second cannula and needle each includes an elongated slot extending between distal and proximal ends thereof, and are relatively rotatable to align the elongated slot in the needle with the elongated slot in the channel of the second cannula for selective confinement and release of the conductive lead disposed therein.

8. The apparatus according to claim 3 in which the channel of the second cannula is disposed eccentric the suction port within the visual field of the endoscope.

9. Apparatus for performing a surgical procedure on the heart of a patient under visualization through an endoscope, the apparatus comprising:

a surgical instrument for receiving the endoscope and configured for forming a working cavity through the tissue between a subxiphoid entry location and the heart;

the surgical instrument including a suction port near a distal end thereof for establishing a suction attachment to a target site on the epicardium below the pericardium under visualization through the endoscope; and

a device slidably disposed within the surgical instrument for contacting the epicardium below the pericardium at a location referenced to the target site

of the suction attachment for performing a surgical procedure thereat under visualization through the endoscope.

10. The apparatus according to claim 9 in which the device is configured for penetrating myocardial tissue of the heart at the referenced location.

11. The apparatus according to claim 10 in which the device includes a needle for penetrating myocardial tissue at the referenced location to a selected depth.

12. The apparatus according to claim 11 in which the needle is configured for injecting material through the needle into myocardial tissue.

13. The apparatus according to claim 12 in which the needle is configured for injecting undifferentiated satellite cells or myocytes or stem cells at a site of a previous infarct in the myocardium.

14. The apparatus according to claim 11 in which the device is configured for placement of a conductive lead into the penetrated myocardial tissue for providing electrical pacing or defibrillation of the heart.

15. The apparatus according to claim 14 in which the conductive lead is confined within the needle having an elongated slot therein between proximal and distal ends thereof; and

a support for the needle having an elongated slot therein as being rotatable relative to the needle for aligning the slots in the needle and support for selective confinement and release of the conductive lead disposed therein.

16. The apparatus according to claim 9 in which the device for contacting the heart is configured for applying an ablation probe to the epicardial surface.

17. The apparatus according to claim 11 in which the needle includes a penetration indicator for providing sensory indication of depth of penetration.

18. The apparatus according to claim 17 in which the penetration indicator provides indication visible through the endoscope of the depth of needle penetration.

19. The apparatus according to claim 17 in which the penetration indicator includes a segment of the needle of expanded dimension at a location thereon that is proximal a distal end for providing tactile feedback indicative of the depth of penetration to said segment.

20. The apparatus according to claim 9 in which the device slidably disposed within the surgical instrument is laterally displaced from the suction port.

21. The apparatus according to claim 9 in which the suction port is substantially concentrically disposed at a distal end of the surgical instrument.

22. The apparatus according to claim 9 in which the surgical instrument is substantially rigid for applying downward force at the site on the epicardial surface at which suction attachment is established for deforming myocardium thereat substantially perpendicular to the orientation of contact therewith.

23. The apparatus according to claim 9 in which the suction port is laterally displaced from, and within the visual field of the endoscope.

24. Surgical apparatus comprising:

an elongated cannula having first and second separate channels therein and including a suction port at a distal end of the elongated cannula in fluid communication with the first lumen; and

the second lumen having a distal end thereof displaced from the suction port for slidably extending a surgical instrument therethrough forward of the suction port.

25. Surgical apparatus as in claim 24 in which the second lumen is disposed eccentric the first lumen and is dimensioned for slidably supporting a needle therein to selectively extend a distal end of the needle forward of the suction port.

26. Surgical apparatus according to claim 24 in which the second channel includes an elongated slot therein between distal and proximal ends thereof, and dimensioned for slidably and rotatably supporting therein a needle including an elongated slot therein between distal and proximal ends thereof to selectively extend the distal end of the needle forward of the suction port.

27. Surgical apparatus as in claim 24 in which the second lumen is substantially concentrically disposed within the first lumen for slidably supporting a surgical instrument in the second lumen to extend forward of the suction port.

28. Surgical apparatus as in claim 27 in which the suction port includes an annulus area at the distal end of the elongated cannula surrounding the second lumen to form a contact surface for suction attachment thereof to a surface of a bodily organ.

29. Surgical apparatus as in claim 24 in which the surgical instrument comprises a needle dimensioned to slide within the second lumen and includes a distal end skewed from perpendicularity to form a sharpened substantially planar end surface having a length not greater than about 3 times the diameter dimension of the needle.

30. Surgical apparatus as in claim 24 in which the surgical instrument includes a needle dimensioned to slide within the second lumen and to penetrate the myocardium of the heart, and including a penetration indicator disposed relative to the distal end of the needle to provide indication of depth of penetration of the myocardium.

31. Surgical apparatus as in claim 30 in which the penetration indicator includes a band disposed about the needle at a location proximal the distal end of the needle to provide visual indication of depth of penetration into the myocardium.

32. Surgical apparatus as in claim 30 in which the penetration indicator includes a segment of the needle having extended diametric dimension to provide tactile indication of increased resistance to penetration of the myocardium at a depth of penetration related to the location of the segment with respect to the distal end of the needle.

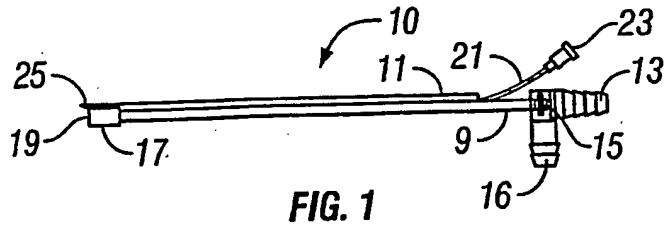

FIG. 1

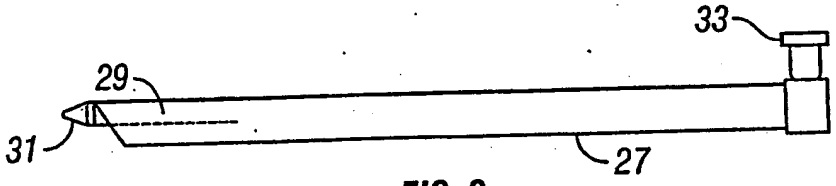

FIG. 2

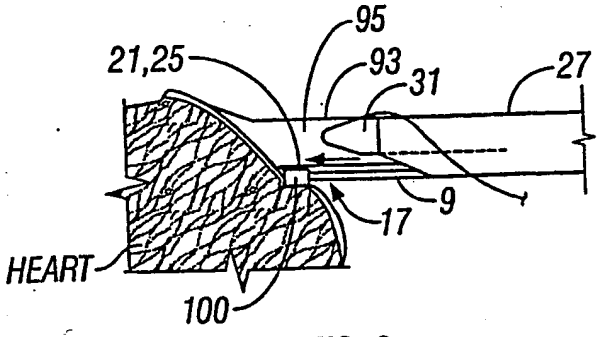

FIG. 3

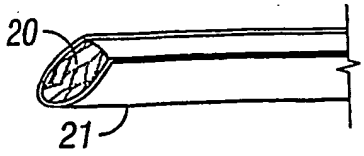

FIG. 4A

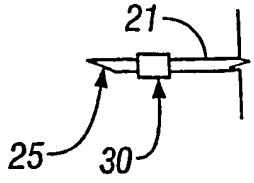

FIG. 4B

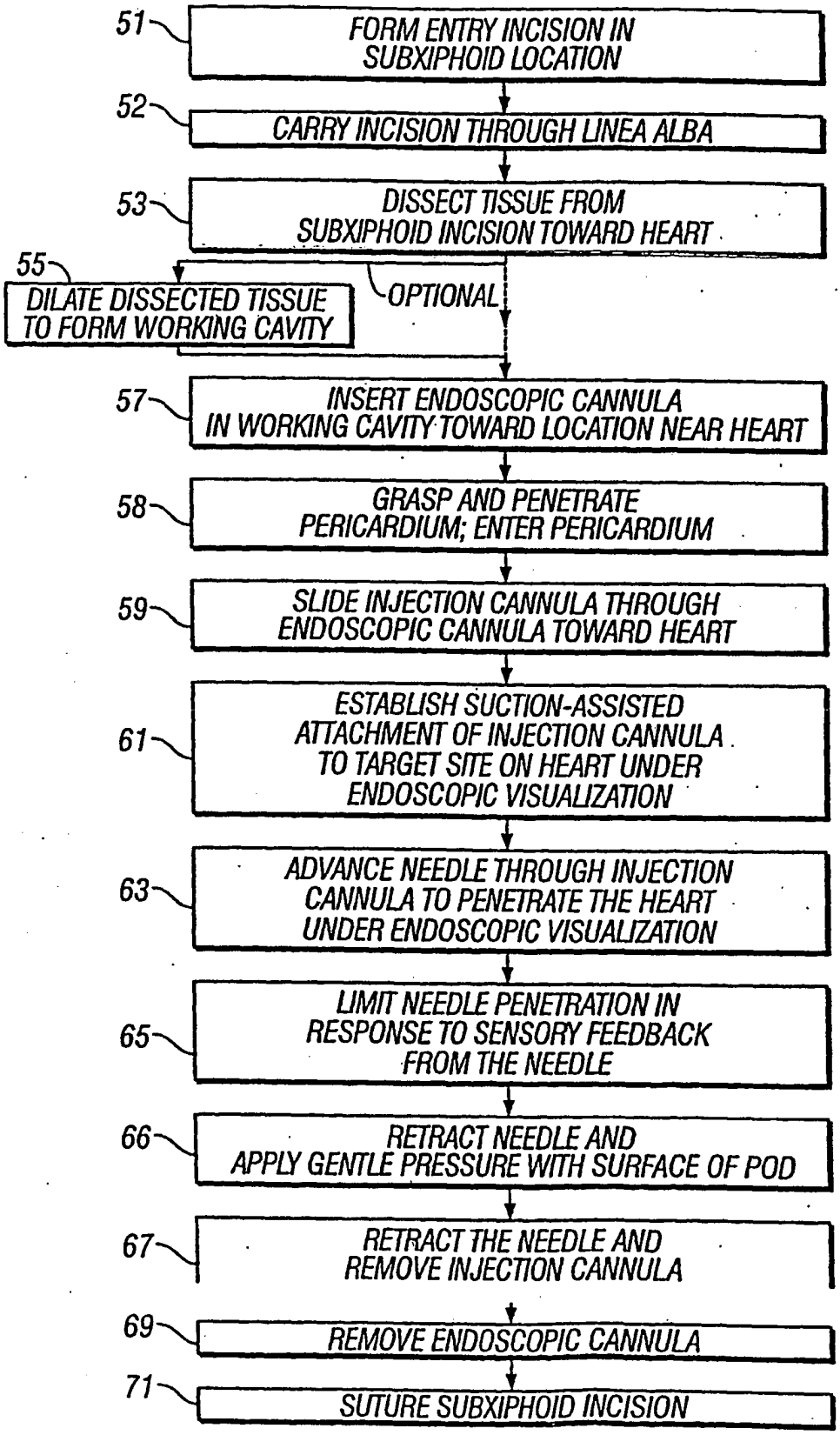
51
FORM ENTRY INCISION IN SUBXIPHOID LOCATION
52
CARRY INCISION THROUGH LINEA ALBA
53
DISSECT TISSUE FROM SUBXIPHOID INCISION TOWARD HEART
55
DILATE DISSECTED TISSUE TO FORM WORKING CAVITY
OPTIONAL
57
INSERT ENDOSCOPIC CANNULA IN WORKING CAVITY TOWARD LOCATION NEAR HEART
58
GRASP AND PENETRATE PERICARDIUM; ENTER PERICARDIUM
59
SLIDE INJECTION CANNULA THROUGH ENDOSCOPIC CANNULA TOWARD HEART
61
ESTABLISH SUCTION-ASSISTED ATTACHMENT OF INJECTION CANNULA TO TARGET SITE ON HEART UNDER ENDOSCOPIC VISUALIZATION
63
ADVANCE NEEDLE THROUGH INJECTION CANNULA TO PENETRATE THE HEART UNDER ENDOSCOPIC VISUALIZATION
65
LIMIT NEEDLE PENETRATION IN RESPONSE TO SENSORY FEEDBACK FROM THE NEEDLE
66
RETRACT NEEDLE AND APPLY GENTLE PRESSURE WITH SURFACE OF POD
67
RETRACT THE NEEDLE AND REMOVE INJECTION CANNULA
69
REMOVE ENDOSCOPIC CANNULA
71
SUTURE SUBXIPHOID INCISION

FIG. 6

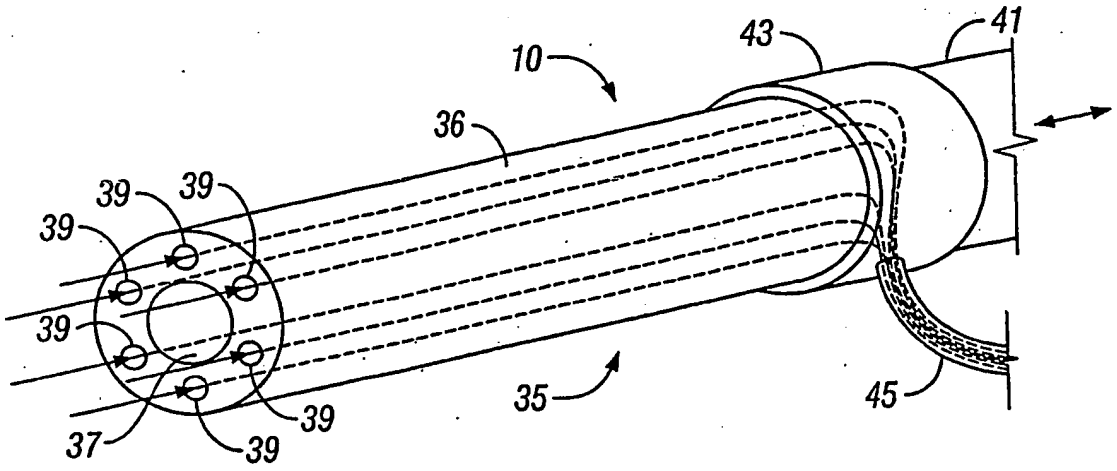

FIG. 5

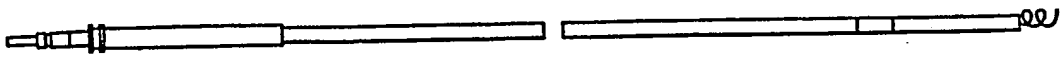

FIG. 7

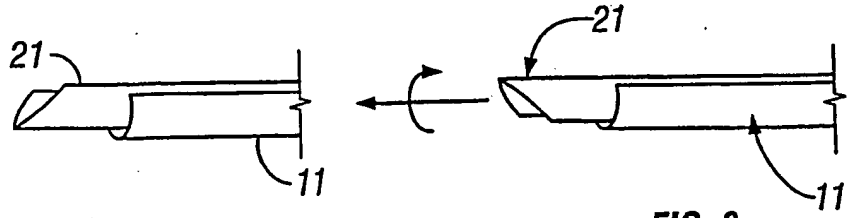

FIG. 8

FIG. 9

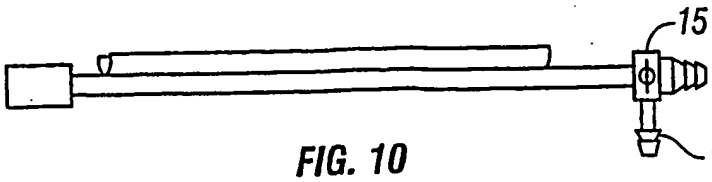

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/13614

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/32; 19/00
US CL : 606/170, 129

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/170, 129, 167, 172, 179

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 6,102,046 A (WEINSTEIN et al) 15 August 2000 (15.08.2000), see whole document	1, 2, 9, 10, 16, 20-25, 27 and 28 --- 3-6, 8, 11-14, 17-19, 29-32
Y	US 6,322,536 B1 (ROSENGART et al.) 27 November 2001 (27.11.2001), see whole document	3-5, 8, 11-13, 17-19, 29-32
Y	US 5,902,331 A (BONNER et al.) 11 May 1999 (11.05.1999), see whole document	3, 6, 11, 14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 July 2003 (25.07.2003)	15 AUG 2003
Name and mailing address of the ISA/US *Mail Stop PCT, Attn: ISA/US* Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Jessica R Baxter Telephone No. 703-308-0858

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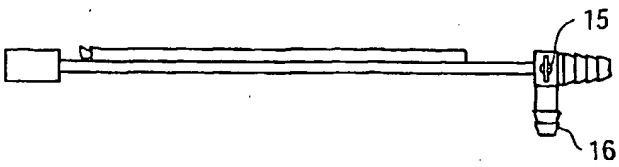
WO 03/105706 A1

(54) Title: RELEASABLE GUIDE AND METHOD FOR ENDOSCOPIC CARDIAC LEAD PLACEMENT



(57) Abstract: Apparatus and surgical methods establish temporary suction attachment to a target site on the surface of a bodily organ for enhancing accurate placement of a surgical instrument (41) maintained in alignment with the suction attachment. A suction port (19) on the distal end of a supporting cannula (10) provides suction attachment to facilitate accurate positioning of a needle (21) for injection penetration of tissue at the target site or for anchoring a cardiac electrode (97) on the moving surface of a beating heart. Force applied via the suction attachment to the surface of the heart selectively distorts the myocardium for angularly orienting and accurately positioning a surgical instrument (41) or cardiac electrode (97) thereon.

RELEASABLE GUIDE AND METHOD FOR ENDOSCOPIC CARDIAC LEAD PLACEMENT

Field of the Invention:

[0001] This invention relates to endoscopic cardiovascular surgical procedures and instruments, and more particularly to apparatus including a vacuum-assisted cannula and surgical instruments operable therewith, and to surgical procedures utilizing such apparatus.

Background of the Invention:

[0002] The injection of undifferentiated satellite cells or myocytes or stem cells into the myocardium of a beating heart in the endoscopic procedure of cellular cardiomyoplasty must be performed carefully to avoid complications. A specialized instrument, as described in the aforecited applications, is advanced through an operating channel of an endoscopic cannula to deliver cells in controlled manner into a beating heart. If a needle is used to inject the cells, sufficient control must be provided to ensure that the needle does not puncture a coronary vein or artery and cause hemorrhage within the pericardial space, with subsequent cardiac tamponade. Movement of the beating heart further complicates needle placement because of erratic movement of the coronary vessels as needle insertion is attempted. Similarly, placement of other elements such as epicardial pacing or defibrillation leads into the myocardium of a beating heart must be carefully placed to avoid puncture of a coronary vein or artery with concomitant complications.

Summary of the Invention:

[0003] In accordance with the illustrated embodiments of the present invention, a substantially rigid cannula includes separate elongated lumens

extending between distal and proximal ends of the cannula to provide an instrument channel and one or more separate vacuum channels that terminate in a suction port located adjacent the distal end of the cannula. The instrument channel is sized to accommodate various surgical instruments including a hollow needle for penetrating the myocardium to deliver the cells. The needle is configured for shallow penetration to avoid puncturing into a chamber of the heart with associated complications. In an alternative embodiment, an instrument channel carried by a 'needle' is sized to accommodate epicardial pacing or defibrillating leads. Additionally, the cannula with separate lumens or channels therethrough may be incorporated with or disposed within an instrument channel of an endoscopic cannula that houses an endoscope aligned with a distal transparent tip. This assemblage of surgical instruments may be conveniently positioned through tissue disposed between a subxiphoid incision and a surgical site on the epicardium of a beating heart, or positioned through tissue disposed between a thoracotomy incision and a surgical site on the epicardium of a beating heart. In some cases, a laterally expandable sheath may be employed to form a working cavity in tissue to facilitate the placement of the vacuum port and associated instrument channel at the surgical site on the epicardium, as described in the aforecited related applications. In another embodiment of the present invention, a guide tube carries a suction tube slidably therein and supports a lead-placing channel thereon which includes rotatable or slidable half sections that house a cardiac pacing or defibrillating lead. The lead-placing channel can be configured to enclose a cardiac lead and to release the lead along a longitudinal slot therein that results from reconfiguring the channel after placement of a distal end of the cardiac lead into the myocardium. The suction tube terminates as its distal end in a suction pod that can provide temporary suction attachment of the assembly at a selected surgical location on the myocardium of a beating heart while a cardiac

lead is manipulated within the placement channel to anchor the distal end of the cardiac lead to the myocardium.

Brief Description of the Drawings:

[0004] Figure 1 is a side view of a vacuum-assisted insertion cannula in accordance with one embodiment of the present invention;

[0005] Figure 2 is a side view of an endoscopic cannula for use with the insertion cannula of Figure 1;

[0006] Figure 3 is a partial side view of the assembled cannulas of Figures 1 and 2 in a surgical procedure;

[0007] Figure 4a is a partial side view of a split needle according to one embodiment of the present invention;

[0008] Figure 4b is a partial side view of a needle with short bevel sharpened tip according to an embodiment of the present invention;

[0009] Figure 5 is a perspective view of another embodiment of an insertion cannula in accordance with the present invention;

[0010] Figures 6a and 6b comprise a flow chart illustrating a surgical procedure in accordance with the present invention;

[0011] Figure 7 is a plan view of an epicardial lead with screw-in distal tip and attached proximal connector;

[0012] Figure 8 is a partial plan view of a needle in one configuration incorporating an open instrument channel for placement of an epicardial lead;

[0013] Figure 9 is a partial plan view of the needle of Figure 8 in a complementary configuration incorporating a closed instrument channel;

[0014] Figure 10 is a plan view of a cannula with attached instrument channel;

[0015] Figure 11 is a plan view of a releasable guide for a cardiac lead according to another embodiment of the present invention;

[0016] Figure 12 is a partial plan view of the distal end of the releasable guide in the embodiment of Figure 11;

[0017] Figure 13 is a partial plan view of the proximal end of the releasable guide in the embodiment of Figure 11;

[0018] Figure 14 is a top view of the distal end of the releasable guide in the embodiment of Figure 11;

[0019] Figure 15 is a perspective view of the distal end of the releasable guide according to the embodiment illustrated in Figure 11;

[0020] Figure 16 is a partial plan view of a releasable guide in accordance with the embodiment illustrated in Figure 11;

[0021] Figure 17 is a partial plan view of the releasable guide of Figure 11 assembled with an endoscopic instrument;

[0022] Figure 18 is a sectional view of the releasable guide of Figure 16;

[0023] Figure 19 is a partial plan view of one embodiment of the proximal end of the guide channel of the releasable guide of Figure 16;

[0024] Figure 20 is an end view of the proximal end of the guide channel of Figure 16; and

[0025] Figures 21a and 21b comprise a flow chart illustrating a surgical procedure for implanting a cardiac lead in accordance with the present invention.

Detailed Description of the Invention:

[0026] Referring now to Figure 1, there is shown one embodiment of a suction assisted insertion cannula 10 according to the present invention including a closed channel 9 and a superior channel 11 attached to the closed channel. The closed channel 9 includes a suitable hose connection 13 and a three-way vacuum control valve 15 including an irrigation port 16 at the proximal end, and a suction pod 17 positioned on the distal end. The suction

pod 17 includes a porous distal face or suction ports 19 that serves as a vacuum port which can be positioned against the epicardium to facilitate temporary fixation thereto as a result of the reduced air pressure of vacuum supplied to the suction pod 17. The distal end of the superior instrument channel 11 that is attached to the closed channel 9 may thus be held in accurate fixation in alignment with a selected surgical site on the epicardium relative to the suction fixation location of the suction pod 17 on the epicardium. A rounded smooth surface of suction pod 17 may be used to apply gentle pressure on the epicardium to stop bleeding at small puncture sites, or to allow injected cells to be absorbed without exiting back out of the injection.

[0027] The superior channel 11 is sized to accommodate slidable movement therein of a hollow needle 21 that may exhibit lateral flexibility over its length from the needle hub 23 at the proximal end to the sharpened distal end 25. When used to inject cells, the needle 21 may be about 22-25 gauge in diameter and includes an internal bore of sufficient size to facilitate injection of cells without incurring cell damage, or lysis. When used to place pacing or defibrillating leads, the needle 21 may be about 2-2.5 mm in diameter with an internal bore of sufficient size to accommodate a lead of diameter up to approximately 2 mm in diameter.

[0028] Due to the relatively large diameter of the needle for epicardial lead placement (approximately 2-2.5 mm in diameter), a solid obturator 20 may optionally be used with the slotted needle 21, as illustrated in Figure 4a, for insertion into the myocardium. The obturator 20 closes off the distal end of the needle, to prevent the needle from coring out a section of the myocardium during needle insertion, with associated excessive bleeding. The obturator 20 may be removed from the needle 21 after needle insertion and the epicardial lead advanced into the myocardium. The epicardial lead, as illustrated in

Figure 7, is flexible and may be positioned within its own split sheath or tube for easier insertion through the slotted needle.

[0029] After the lead is implanted in the heart by the procedure described above, the proximal end is disposed out through the small initial incision in the patient. The proximal end may then be tunneled subcutaneously from the initial incision to an incision in the patient's upper chest where a pacemaker or defibrillator will be located. A small, elongated clamp is passed through the subcutaneous tunnel to grasp the proximal end of the epicardial lead to facilitate pulling the lead through the tunnel for placement and attachment to the pacemaker or defibrillator.

[0030] Both the superior channel 11 and the needle 21 may be longitudinally slotted for placing an epicardial lead that may incorporate a large diameter connector, as illustrated in Figure 7. A split sheath can be used around the lead to facilitate advancement and rotation of the lead via the slotted needle. After anchoring such lead in the myocardium, for example by screwing in the distal tip, the slotted needle 21 is rotated to align its slot with the slot in the superior channel 11, thus allowing the lead to be released from the cannula.

[0031] The structure according to this embodiment of the invention, as illustrated in Figure 1, is disposed to slide within the instrument channel in an endoscopic cannula 27, as shown in Figure 2. This cannula includes an endoscope 29 therein that extends from a tapered transparent tip 31 attached to the distal end, to a viewing port 33 at the proximal end that can be adapted to accommodate a video camera. In this configuration, the structure as illustrated in Figure 1 may be positioned within the instrument channel in the cannula 27 of Figure 2 to position the suction pod 17 and sharpened needle tip 25 in alignment with a surgical target on the heart, as illustrated in Figure 3. The suction pod 17 is temporarily affixed to the epicardium in response to suction

applied to the porous face 19 of the suction pod 17 under control of a suction valve 15, and the sharpened tip 25 of the needle 21 may then be advanced to penetrate into the myocardium at an accurately-positioned surgical site, all within the visual field of the endoscope 29 through the transparent tip 31. Following injection, the needle is withdrawn and the suction pod 17 may be rotated or otherwise manipulated to position a surface thereof on the injection site with gentle pressure to allow time for the injected cells to be absorbed and to control any bleeding occurring out of the injection site.

[0032] As illustrated in Figures 2 and 3, the various channels in the endoscopic cannula 27 and the insertion cannula 10 have specific orientations with respect to each other in order to provide stabilization of the epicardial surface and allow visual control of the injection process. In the endoscopic cannula 27, the instrument channel is positioned below the endoscopic channel and this allows the cannula 27 and the transparent tapered tip 31 on the endoscope 29 to retract the pericardium away from the epicardial surface of the heart at the operative site. This creates a space 95 for contacting the heart below the pericardium, as illustrated in Figure 3. As the cell insertion cannula 9 is advanced forward out of the instrument channel of the endoscopic cannula 27, the suction pod 17 is visualized through the endoscope 29 and transparent tip 31, as the suction pod 17 is placed on the epicardial surface of the heart. At a selected site on the heart, for example, at the site of an old myocardial infarct, the suction is activated to attach the pod 17 to the heart. The configuration of the instrument channel of the cell insertion cannula 10 on top of the suction channel 9 allows the needle 21 to be visible as soon as it exits from the instrument channel, and remain visible within the visual field of the endoscope along the entire path of travel of the needle 21 from the insertion cannula 10 to its insertion into the myocardium. Continuous visualization of

the needle 21 in this manner helps to prevent inadvertent puncture of a coronary vessel.

[0033] The configuration of the suction pod 17 and the needle 21 on the insertion cannula 10 also facilitates delivery of substances or devices in an orientation perpendicular to the epicardial surface. For placement of pacing or defibrillation leads, it is particularly desirable to have the leads enter the myocardium in an orientation that is generally perpendicular to the epicardial surface for secure anchoring in the myocardium. Generally, the insertion cannula 10 is advanced through the endoscopic cannula 27 and approaches the epicardial surface of the heart at a tangential angle. Accordingly, the insertion cannula 10 is configured to facilitate deforming the epicardial surface in order to achieve perpendicular entry of the needle 21 into the myocardium, as illustrated in Figure 3. The suction pod 17 of the insertion cannula 10 temporarily attaches to the epicardial surface upon application of vacuum under control of the valve 15. Downward pressure can be exerted on the epicardial surface via the substantially rigid insertion cannula 10. The pliable myocardium thus deforms to create a surface ledge 100 distal to the suction pod 17 oriented perpendicular to the axis of the superior instrument channel 11 of the insertion cannula 10, as illustrated in Figure 3. As the needle 21 is advanced, it enters the myocardium generally perpendicularly to the epicardial surface as thus deformed for desirable lead placement or cell injection.

[0034] Referring now to Figures 3 and 4b, it should be noted that the insertion cannula 10 is sized to fit in slidable orientation within the working channel of about 5-7 mm diameter in the endoscopic cannula 27. The outer dimensions of the suction pod 17 are less than 5-7 mm diameter and is configured on the distal end of the closed channel 9 not to obstruct the forward movement of the needle 21 past the closed, back surface 19 of the suction pod 17.

[0035] As illustrated in Figure 4b, the sharpened distal end 25 of the needle 21 includes a relatively short, sharpened bevel of length approximately 2-3 times the diameter of the needle. The short bevel length of the needle assures that cells are injected within the myocardium, and that part of the needle bevel does not extend into a heart chamber, with resultant intracardiac cell delivery. A visual and tactile marker 30 of extended diameter may be incorporated into the distal portion of the needle 21. As the needle is advanced into the myocardium, the marker 30 of enlarged diameter offers increased resistance to tissue insertion. The marker 30 is positioned just proximal to the bevel of the needle and extends proximally a distance of approximately 5-7 mm.

[0036] A needle stop may also be built into the proximal end of the needle 21. Such a stop may simply be the hub 23 of the needle, and the needle 21 may be sufficiently limited in length that only a specific length of needle, for example 1 cm, may extend out of the instrument channel of the cell insertion cannula 10 when the needle hub 23 abuts against the proximal face of the instrument channel 11. However, the distal visual and tactile marker 30 provides generally more precise guide to depth of needle penetration under conditions of different angles of possible needle insertion with respect to the epicardial surface. With an extremely shallow angle of entry, a needle of short length may not enter the heart at all. In use, the transparent tip 31 and the suction pod 17 of the assembled cell injection device may be manipulated to reshape a localized portion of the epicardial surface of the heart to allow perpendicular entry of the needle into the myocardium, as illustrated in Figure 3. With the suction pod 17 activated, gentle manipulation of the insertion cannula allows adjustment of the needle entry angle while maintaining temporary vacuum-assisted attachment to the epicardial surface, as shown in Figure 3.

[0037] The insertion device may also inject substances other than cells. Angiogenic agents such as vascular endothelial growth factor (VEGF) may be injected into myocardial scar tissue in an attempt to stimulate neovascularization, or growth of new blood vessels into the area. Insertion of the needle itself into myocardial tissue may be therapeutic as a form of transmyocardial revascularization (TMR). It is believed that needle insertion injury may stimulate angiogenesis, or growth of new vessels into a devascularized portion of the heart. The cell insertion cannula thus promotes accurate placement of a needle 21 into myocardium under continuous visualization. When combined with the endoscopic cannula, the needle placement may be accomplished through a small, 2 cm subxiphoid skin incision.

[0038] The illustrated embodiment of the insertion cannula includes a substantially rigid cannula containing a closed channel 9 ending in a distal suction pod 17, and a superior instrument channel 11 ending immediately proximal to the suction pod 17 on the closed channel 9. In operation, a long needle is advanced through the instrument channel 11. The needle 21 contains a marker 30 immediately proximal to its beveled tip 25 that serves as a visual or other sensory indicator of the depth of needle insertion. The marker 30 may be a segment of expanded diameter to provide tactile feedback upon insertion into myocardial tissue. For example, a gold-colored metallic sleeve 30 may be welded or soldered onto the needle 21 to provide both visual and tactile feedback of the depth of penetration of the needle tip into the myocardium. The marker may alternatively include a series of rings etched in the needle or a band etched or sandblasted in the same area. A three-way valve 15 on the cannula 9 allows suction in the pod 17 to be turned on or off, and allows irrigation fluid such as saline to be injected through the suction pod 17 while suction is turned off.

[0039] Referring now to Figure 5, there is shown a perspective view of another embodiment of an insertion cannula 35 similar to insertion cannula 10 described above, including an elongated body 36 having a central bore 37 there through to serve as an instrument channel, and including one or more eccentric channels 39 that serve as suction conduits. The central bore may be sized to slidably support surgical instruments 41 therein such as tissue cutters and dissectors, electrocoagulators, injection needles, and the like. For example, surgical instrument 41 may be an energy-supplying ablation probe for epicardial ablation of myocardial tissue in the treatment of cardiac arrhythmia such as atrial flutter or atrial fibrillation. The ablation probe 41 may use radio frequency, microwave energy, optical laser energy, ultrasonic energy, or the like, to ablate myocardial tissue for arrhythmia correction. The suction pod 17 attaches to the epicardial surface while suction is turned on at valve 15 to facilitate advancing the ablation probe 41 through the cannula 35 into contact with the heart at the desired site under direct endoscopic visualization for precise myocardial ablation.

[0040] The left atrial appendage is frequently the site or source of thromboemboli (blood clots) that break away from the interior of the left atrial appendage and cause a stroke or other impairment of a patient. An ablation probe 41 can be used in the cannula 35 to shrink and close off the appendage to prevent thromboemboli from escaping.

[0041] In a similar procedure, a suture loop or clip can be placed through the cannula 35 and applied tightly around the atrial appendage to choke off the appendage.

[0042] The suction channels 39 in the cannula 35 of Figure 5 may form a suction attachment surface at the distal end of the cannula 35, or may be disposed in fluid communication with a suitable suction pod with a porous distal face and with a central opening in alignment with the central bore 37.

The suction-attaching distal face provides an opposite reaction force against a tool that exerts a pushing force such as a needle, screw-in lead tip, or other device deployed through the central bore 37 of the cannula 35. The proximal ends of the eccentric channels 39 are connected via a manifold or fluid-coupling collar 43 to a vacuum line 45. Alternatively, a single channel 39 may communicate with an annular recess or groove disposed concentrically about the central bore 37 within the distal end to serve as a suction-assisted attachment surface.

[0043] In this configuration, an injection needle 21 slidably disposed within the central bore 37 may be extended beyond the distal end of the cannula 35, within the visual field of an endoscope, in order to orient the needle in alignment with a surgical target site on the pericardium prior to positioning the distal end of the cannula on the pericardium and supplying suction thereto to temporarily affix the cannula 35 in such position. A cannula 35 formed of transparent bioinert material such as polycarbonate polymer facilitates visual alignment of the cannula 35 and the central bore 37 thereof with a surgical site, without requiring initial extension of a surgical instrument, such as a cell-injection needle, forward of the distal end within the visual field of an endoscope. In an alternative embodiment, the central lumen or bore 37 may serve as a suction lumen with multiple injection needles disposed in the outer lumens 39.

[0044] Referring now to the flow chart of Figures 6a, 6b, the surgical procedure for treating the beating heart of a patient in accordance with one embodiment of the present invention proceeds from forming 51 an initial incision at a subxiphoid location on the patient. The incision is extended 52 through the midline fibrous layer (linea alba). The tissue disposed between the location of subxiphoid incision and the heart is bluntly dissected 53, for example, using a blunt-tip dissector disposed within a split-sheath cannula of

the type described in the aforecited patent application. The channel thus formed in dissected tissue may optionally be expanded 55 by dilating tissue surrounding the channel, for example, using a balloon dilator or the split-sheath cannula referenced above, in order to form a working cavity through the dissected and dilated tissue, although this may be unnecessary.

[0045] An endoscopic cannula, for example, as illustrated in Figure 2 including an endoscope and a lumen for receiving surgical instruments therein is inserted 57 into the working cavity through the subxiphoid incision toward the heart to provide a field of vision around a target site on the heart, and to provide convenient access via the lumen for surgical instruments of types associated with surgical procedures on the heart. The first such instrument is the pericardial entry instrument, as described in the aforementioned provisional applications, which generally grasp the pericardium in a side-bite manner to form an elevated ridge of tissue through which a hole can be safely formed without contacting the epicardial surface. Once the pericardium is penetrated 58, other instruments can be inserted through the hole and into the working space 58. One such instrument is an insertion cannula, for example, as illustrated in Figure 1, that includes a suction channel and an instrument channel and is slidably supported 59 within the instrument lumen of the endoscopic cannula. The suction channel of such instrument extends through the length thereof from a proximal end to a suction pod at the distal end that can be extended into contact 61 with the beating heart of the patient at a selected target site. The suction pod can be carefully positioned on the epicardium under visualization through the endoscope, and the suction can be applied to establish temporary attachment of the injection cannula to the epicardium. A needle or other surgical instrument such as surgical scissors or an electrocauterizer, or the like, is then moved into contact 63 with the epicardium to perform a surgical procedure at or near the target site. One

surgical procedure includes penetrating the epicardium and myocardial tissue with the needle, typically in a region of a previous infarct, to stimulate transmyocardial revascularization or to inject undifferentiated satellite cells to promote regrowth of scarred myocardial tissue. During such surgical procedure, it is important to limit the depth of penetration of the needle in order to assure injection penetration only into the myocardium, and to avoid puncture into a heart chamber. A penetration indicator 30 may be disposed about the needle near the distal end thereof to provide visual and/or tactile feedback as mechanisms for limiting 65 the depth of needle penetration, as illustrated in Figure 4b. Specifically, visualization of the penetration indicator via the endoscope facilitates control of manual extension of the needle into the myocardium. Additionally, an indicator of increased diameter disposed about the needle at an appropriate position proximal the distal end serves as a penetration indicator by providing increased tactile feedback of limiter by increasing the resistance to insertion of the needle into the myocardium. After needle penetration and cell injection, the suction pod 17 may be manipulated to apply gentle pressure 66 at a surface thereof to the injection site to allow cell absorption and to tamponade any bleeding from the injection site.

[0046] After one or more injections of the myocardium, positioned and performed as described above, the injection cannula and the needle supported therein are removed 67 through the instrument lumen of the endoscopic cannula which is then also retrieved 69 from the working cavity, and the initial subxiphoid entry incision is then sutured closed 71 to conclude the surgical procedure.

[0047] The endoscopic cannula and pericardial entry instrument may also be applied from a thoracotomy incision to gain access to the heart. A 2 cm incision is performed in an intercostal space in either the left or the right chest. Ideally, the incision is made between the midclavicular line and the anterior to

mid axillary line. The incision is extended through the intercostal muscles and the pleura, until the pleural cavity is entered. The endoscopic cannula is then inserted into the pleural cavity and advanced to the desired area of entry on the contour of the heart, visualized within the pleural cavity. The pericardial entry instrument and procedure as described in the aforementioned applications are used to grasp the pleura, and a concentric tubular blade cuts a hole in the pleura, exposing the pericardium underneath. The pericardium is then grasped by the pericardial entry instrument, and the tubular blade is used to cut a hole in the pericardium, allowing access to the heart. The transparent tapered tip 31 of the endoscopic cannula 29 aids in pleural and pericardial entry by retracting lung and pleural tissue that may impede visualization of the pericardial entry site. Once the pericardium is entered, the endoscopic cannula 29 may be moved around to visualize anterior and posterior epicardial surfaces.

[0048] Referring now to plan view of Figure 11, there is shown an assembly of suction tube 81 slidably disposed within a guide tube 83 to which is mounted a lower, slotted segment 85 of a guide channel. An upper, slotted segment 87 of the guide channel is slidably rotatably received within the lower slotted segment 85 and a cardiac pacing or defibrillating lead 89 is housed within the guide channel that is configured in the one orientation of the upper and lower segments as a closed guide channel. Another configuration of the upper and lower segments of the guide channel, as later described herein, forms an open channel or slot, as shown in Figure 14 later described herein, for convenient release of the cardiac lead 89.

[0049] The suction tube includes a suction pod 91 at the distal end thereof and a suction-line connection fitting 93 at the proximal end for convenient hose or tubing attachment to a source of vacuum. Optionally, the connection fitting 93 may include a suction control valve 95 for adjusting the suction attachments of the suction pod to the epicardium of a patient's heart.

[0050] The cardiac pacing or defibrillating lead 89 is slidably and rotatably housed within the guide channel 85, 87 in the closed configuration, and includes a helical or screw-in electrode 97 attached to the distal end of the cardiac lead 89, as illustrated in Figure 12. This greatly facilitates electrically connecting and mechanically anchoring the electrode in the myocardium of a patient's beating heart by rotating and advancing the proximal end 99 of the cardiac lead 89 within the guide channel 85, 87. For this purpose, the cardiac lead 89 exhibits high torsional and compressional rigidity and high lateral flexibility so that the electrode 97 may be accurately manipulated into screw-like attachment to the myocardium via manual manipulation of the proximal end 99 of the cardiac lead 89. Such cardiac lead 89 may include braided multiple strands of wire coated with a layer of insulating material such as Teflon, or the like. The accuracy of placement of the screw-in electrode 97 in the myocardium of a patient's beating heart is significantly enhanced by temporary suction attachment of the suction pod 91 to the pericardium or exposed myocardium. The suction pod 91 includes a suction port 98 that may be disposed in lateral or skewed orientation relative to the elongated axis of the suction tube 81. This facilitates the temporary suction attachment while the electrode 97 at the distal end of the cardiac lead 89 that is slidably guided within the guide channel 85, 87 (which is disposed in substantially fixed axial orientation relative to the suction pod 91 and vacuum tube 81) is being anchored into the myocardium.

[0051] After the electrode 97 on the distal end of the cardiac lead 89 is anchored into the myocardium of a patient's beating heart, the guide channel that houses the cardiac lead 89 may be re-configured into the alternate configuration including a slot along the length of the guide channel, as illustrated in Figure 14, from which the cardiac lead 89 may be easily extracted or released. This open slot configuration may be achieved by sliding the upper

segment 87 proximally along the lower segment 85, as illustrated in Figure 13, or by rotating the upper segment 87 within the lower segment 85, as illustrated in Figure 15. In this way, a longitudinal slot or groove is opened along the entire length of the guide channel that is wide enough to extract the cardiac lead 89 therethrough. This is particularly important for anchoring a cardiac lead 89 of about 2mm diameter that includes a proximal connector 99 which is too large to pass through a guide channel 85, 87 of reasonable interior dimension.

[0052] As illustrated in the perspective view of Figure 15, the suction port 98 in suction pod 91 is oriented in skewed, typically perpendicular, orientation relative to the elongated axis of the guide channel that is formed by the upper and lower segments 87, 85. This facilitates establishing temporary vacuum-assisted attachment of the suction pod 91 to the epicardium, or to myocardium exposed via the entry under the pericardium, that can then be depressed or otherwise distorted by manual application of axial or lateral force at the proximal end of the instrument in order to position the electrode 97 at the proper location and angle for anchoring in the myocardium of the patient's beating heart.

[0053] Referring now to the partial plan view of Figure 16 and the sectional view of Figure 17, there is shown a non-round guide tube 96 that is attached to the lower segment 85 of the guide channel and that slidably supports therein the suction tube 81 of corresponding non-round cross section. In this way, the guide channel formed by segments 85, 87 is retained in substantially parallel axial alignment with the suction tube 81 as the suction pod 91 and the distal end of the guide channel are relatively slidably positioned near and against the epicardium of a patient's heart. In addition, as illustrated in the partial view of Figure 18, the assembly of guide tube 96 and suction tube 81 and guide channel 85, 87 may all be disposed within an

endoscopic cannula 101 having a distal end disposed to facilitate endoscopic viewing of the suction pod 91 and distal end of the guide channel 85, 87. Also, the upper and lower segment 85, 87 of the guide channel may include stepped flanges 103, 105 at the proximal ends thereof, as illustrated in Figures 16, 19 and 20, to facilitate positive orientation of the upper and lower segments 85, 87 in the closed configuration until the upper segment 87 is slid proximally, or slid proximally and rotated, relative to the lower segment 85 in order to re-configure the guide channel in the alternate configuration of an elongated slot along the entire length thereof. As shown in the sectional view of Figure 17, the upper 87 segment can be rotated in the lower segment 85 from the closed configuration in order to align the respective elongated slots 106, 107 sufficiently to release a cardiac lead 89 from within the guide channel.

[0054] In operation, as illustrated in the flow chart of Figures 21a and 21b, the initial surgical procedures are similar to the surgical procedures, as previously described with reference to Figures 6a and 6b, from the initial entry incision 51 through the penetration and entry through the pericardium 58. Thereafter, the releasable guide assembly of section tube 81 and guide channel 85, 87 is slid through the endoscopic cannula 109 toward the heart. The suction pod 91 is advanced into contact with the myocardium through the penetrated pericardium and suction is established to temporarily anchor 110 the suction pod 91 via the suction port 98 at a desired surgical site. A cardiac lead or wire 89 with a screw-in electrode 97 on the distal end of the cardiac lead is positioned at or near the distal end of the guide channel in the closed configuration as the guide channel is advanced 111 toward the desired surgical site adjacent the temporary anchor site of the suction pod 91 on the myocardium. The proximal end of the cardiac lead 89 may now be manually manipulated to screw in the electrode 97 at the distal end into the myocardium

via rotation and urging forward of the cardiac lead 89 to thereby anchor 112 of the cardiac lead 89 in the myocardium.

[0055] The guide channel 85, 87 may now be reconfigured 113 to open an elongated slot along the entire length of the guide channel, and this may be accomplished by sliding the upper segment 87 proximally and completely from the lower segment 85 to thereby release 114 the cardiac lead 89 from within the guide channel 85, 87. Alternatively, the upper segment 87 may be rotated within the lower segment 85 to align the elongated axial slots in each segment to thereby open the guide channel for release of the cardiac lead 89 from within the guide channel 85, 87. Thereafter, the assembly of suction tube 81 and guide channel 85, 87 may be retracted from the endoscopic cannula, and the endoscopic cannula may be removed 115 from within the working cavity, with the cardiac lead 89 in position therein. A subcutaneous tract is formed from the subxiphoid incision to the location of the pacing or defibrillation generator, usually placed in the patient's upper chest, and the cardiac lead is then connected to the generator. The subxiphoid (or other) incision is sutured closed 116 to complete the surgical procedure. Of course, the surgical procedures described above including steps 109-114 may be performed multiple times in order to anchor multiple cardiac leads in the myocardium prior to removing 115 the endoscopic cannula and suturing 116 the initial incision closed.

[0056] Therefore the surgical apparatus and methods of the present invention provide careful placement of an injection needle or other surgical instrument on the surface of a beating heart by temporarily affixing the distal end of a guiding cannula at a selected position on the heart in response to suction applied to a suction port at the distal end. The guiding cannula can be positioned through a working cavity formed in tissue between the heart and a subxiphoid or other entry incision to minimize trauma and greatly facilitate

surgical treatment of a beating heart. Such treatments and procedures may include needle punctures of the myocardium, or injections therein of undifferentiated satellite cells, or other materials, to promote vascularization or tissue reconstruction, for example, at the site of a previous infarct. Such treatments and procedures may also include placing of pacing or defibrillating leads into the myocardium and may further include positioning and manipulating an ablation probe to ablate myocardial tissue for correcting cardiac arrhythmias.

1. Apparatus performing a surgical procedure on the heart of a patient through a working cavity in tissue between the heart and an entry location, the apparatus comprising:

a first cannula including an instrument channel disposed between proximal and distal ends thereof and including an endoscope positioned in the first cannula to provide a visual field forward of the distal end;

the instrument channel of the first cannula being disposed to slidably receive therein an instrument including a guide channel that houses a cardiac lead and that extends between distal and proximal ends thereof, and including a suction port positioned on the distal end of the instrument for contacting a target site on the heart with the suction port;

a suction channel through the instrument connected to the suction port and disposed to connect to a source of suction;

the instrument being slidable within the instrument channel to position the distal end of the guide channel near the heart within the visual field of the endoscope to facilitate anchoring a distal end of the cardiac lead to the heart;

the guide channel being reconfigurable to release the cardiac lead therefrom for leaving the cardiac lead anchored to the heart as the instrument is removed from the working cavity.

2. Apparatus according to claim 1 in which the first cannula is configured for entry into a working cavity from a subxiphoid entry location.

3. Apparatus according to claim 1 in which the guide channel is axially slidable relative to the suction port for extending the distal end of the cardiac lead to contact the heart.

4. Apparatus according to claim 3 in which the distal end of the cardiac lead includes an electrode for penetrating the heart to anchor the electrode therein and provide electrical connection thereto.

5. Apparatus according to claim 4 in which the electrode includes a screw-in member that penetrates the myocardium of the heart to form a conductive connection therein for electrical pacing or defibrillation of the heart.

6. Apparatus according to claim 5 in which the guide channel in the instrument includes an elongated slot extending between distal and proximal ends thereof for selectively releasing the cardiac lead retained therein.

7. Apparatus according to claim 6 in which the elongated slot is exposable by proximally sliding an upper segment of the guide channel relative to a lower segment thereof that is positioned relative to the suction port for exposing the slot in the lower segment between distal and proximal ends thereof.

8. Apparatus according to claim 3 in which the guide channel of the instrument is disposed eccentric the suction port within the visual field of the endoscope.

9. Apparatus for performing a surgical procedure on the heart of a patient through a working cavity in tissue between the heart and an entry incision, the apparatus comprising:

an endoscopic cannula configured for passing through the entry incision and working cavity toward the heart;

a suction attachment supported by the endoscopic cannula for contacting a target site on the heart under visualization through the endoscope;

a cardiac lead supported by the endoscopic cannula for contacting the myocardium below the pericardium at a location referenced to the target site contacted by the suction attachment for attaching the cardiac lead thereat under visualization through the endoscope; and

the support for the cardiac lead is selectably releaseable for leaving the cardiac lead in contact with the myocardium following removal of the endoscopic cannula from the working cavity in the patient.

10. Apparatus according to claim 9 including an instrument having a guide channel for housing the cardiac lead to engage the cardiac lead with myocardial tissue of the heart at the referenced location.

11. Apparatus according to claim 10 in which the cardiac lead for engaging myocardial tissue at the referenced location includes a screw-in electrode at a distal end of the cardiac lead for rotational insertion into the myocardium to a selected depth.

12. Apparatus according to claim 11 in which the cardiac lead extends from a proximal end of the endoscopic cannula to facilitate rotating and advancing the cardiac lead within the guide channel from the proximal end to screw the electrode into myocardial tissue.

13. Apparatus according to claim 12 in which the cardiac lead and electrode are releasable from the guide channel to remain attached to myocardial tissue as the suction attachment and guide channel are removed away from the heart.

14. Apparatus according to claim 10 in which the cardiac lead is confined within the guide channel that includes one elongated segment having an elongated slot therein between proximal and distal ends thereof and includes another elongated segment overlaying the elongated slot, and the guide channel is reconfigurable by moving said another elongated segment relative to said one elongated segment to uncover the elongated slot for releasing the cardiac lead from the guide channel through the slot.

15. Apparatus according to claim 9 in which the referenced location is laterally displaced toward the endoscope from the target site of the suction attachment.

16. Apparatus according to claim 9 in which the endoscopic cannula is substantially rigid for applying force at the site of suction attachment from near a proximal end of the endoscopic cannula for deforming the surface of the heart to alter the angle or position of attachment of the cardiac lead to the myocardium.

17. A surgical instrument comprising:

first and second separate channels and including a suction port at a distal end in fluid communication with the first channel; and

the second channel having a distal end thereof displaced from the suction port for containing a cardiac lead therein in relatively movable orientation with respect to the distal end of the second channel.

18. The surgical instrument as in claim 17 in which the second channel slidably and rotatably supports the cardiac lead therein to selectively extend a distal end of the cardiac lead forward of the suction port.

19. The surgical instrument according to claim 17 in which the second channel comprises a first elongated segment mounted for axial movement relative to the suction port and includes an elongated slot therein between distal and proximal ends thereof, and a second elongated segment overlaying the elongated slot in the first elongated segment and mounted for movement relative thereto for selectively uncovering the elongated slot between distal and proximal ends thereof.

20. The surgical instrument as in claim 19 in which the first and second elongated segments are substantially concentrically disposed to form the second channel for supporting therein the cardiac lead for translational and rotational movement.

21. The surgical instrument as in claim 20 in which the first and second elongated segments include proximal ends that are keyed for unique alignment thereof in one configuration of the guide channel that closes the elongated slot.

22. The surgical instrument as in claim 21 in which the proximal ends of the first and second elongated segments include substantially semi-circular flanges that mate to inhibit relative rotation thereof in the one configuration.

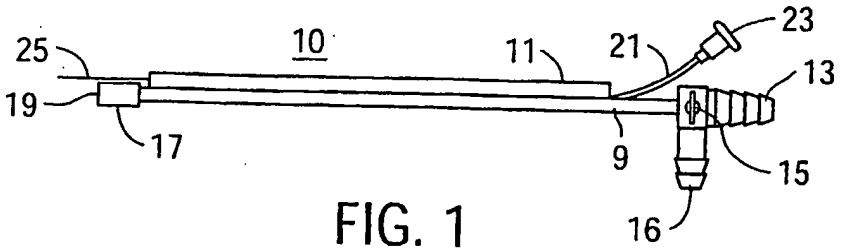


FIG. 1

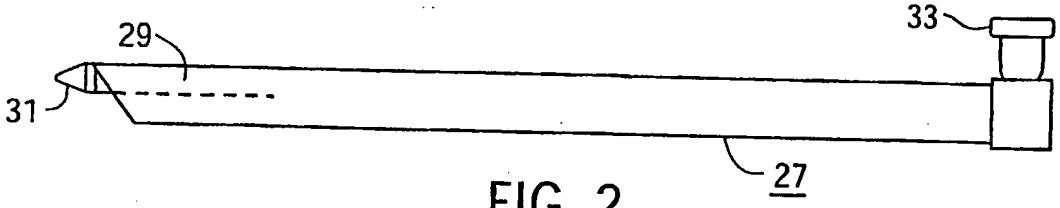


FIG. 2

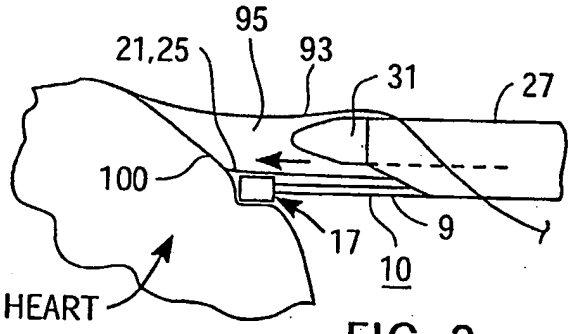


FIG. 3

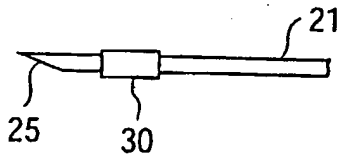


FIG. 4b

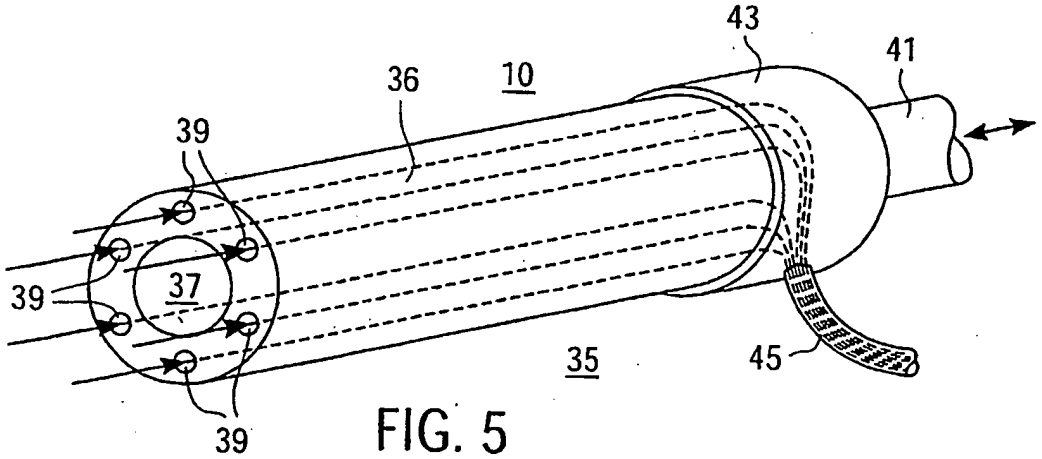


FIG. 5

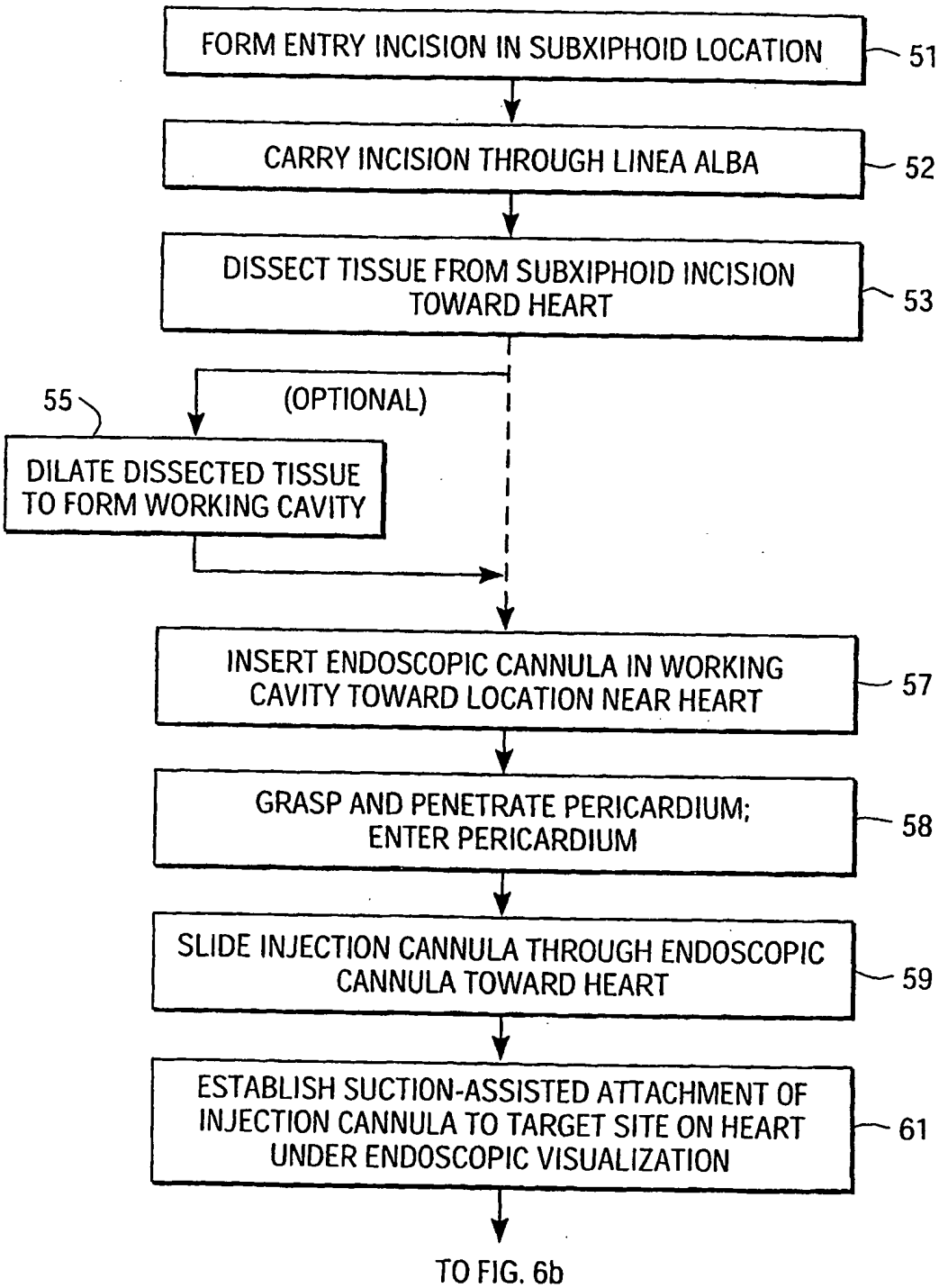

FORM ENTRY INCISION IN SUBXIPHOID LOCATION
51
CARRY INCISION THROUGH LINEA ALBA
52
DISSECT TISSUE FROM SUBXIPHOID INCISION TOWARD HEART
53
55
(OPTIONAL)
DILATE DISSECTED TISSUE TO FORM WORKING CAVITY
INSERT ENDOSCOPIC CANNULA IN WORKING CAVITY TOWARD LOCATION NEAR HEART
57
GRASP AND PENETRATE PERICARDIUM; ENTER PERICARDIUM
58
SLIDE INJECTION CANNULA THROUGH ENDOSCOPIC CANNULA TOWARD HEART
59
ESTABLISH SUCTION-ASSISTED ATTACHMENT OF INJECTION CANNULA TO TARGET SITE ON HEART UNDER ENDOSCOPIC VISUALIZATION
61
TO FIG. 6b

FIG. 6a

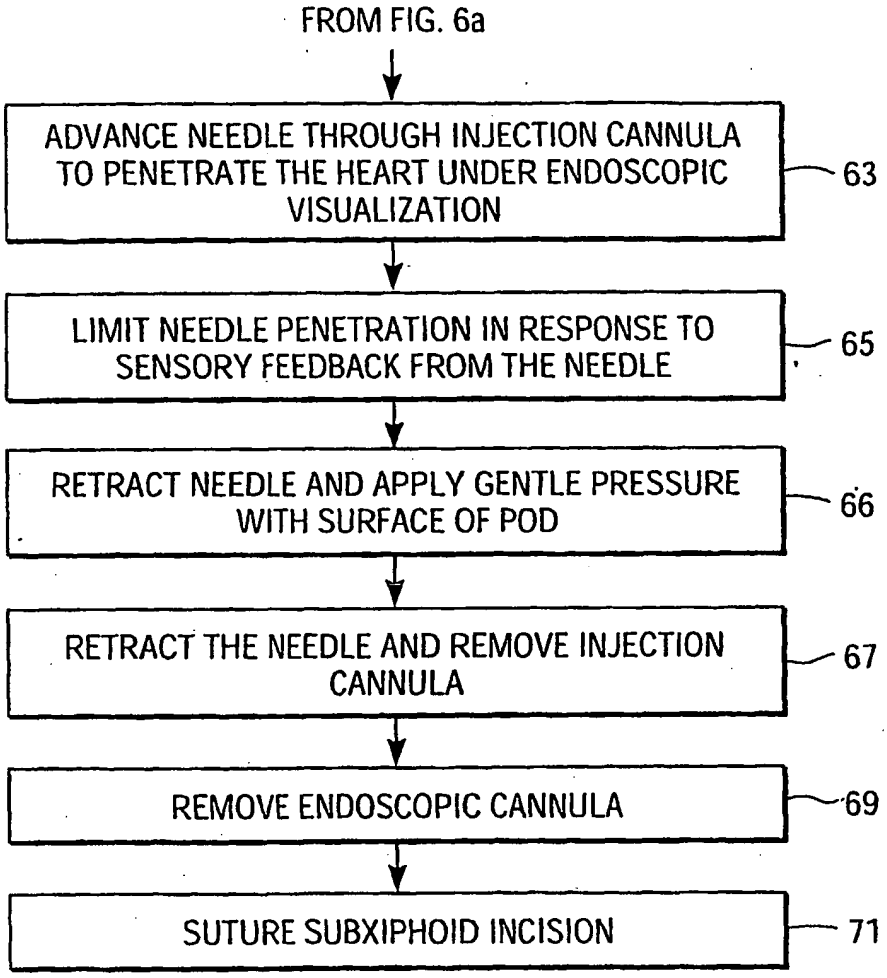

FROM FIG. 6a
ADVANCE NEEDLE THROUGH INJECTION CANNULA TO PENETRATE THE HEART UNDER ENDOSCOPIC VISUALIZATION
63
LIMIT NEEDLE PENETRATION IN RESPONSE TO SENSORY FEEDBACK FROM THE NEEDLE
65
RETRACT NEEDLE AND APPLY GENTLE PRESSURE WITH SURFACE OF POD
66
RETRACT THE NEEDLE AND REMOVE INJECTION CANNULA
67
REMOVE ENDOSCOPIC CANNULA
69
SUTURE SUBXIPHOID INCISION
71

FIG. 6b

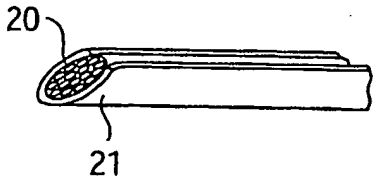


FIG. 4a

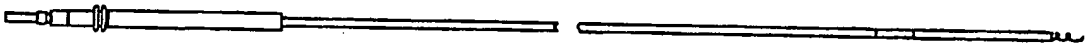


FIG. 7

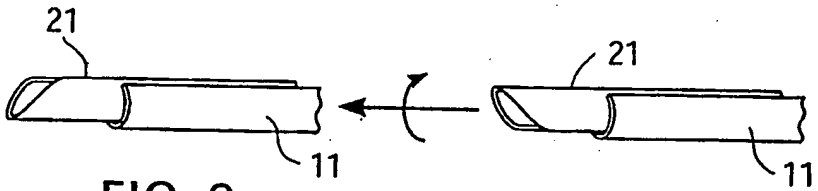


FIG. 8

FIG. 9

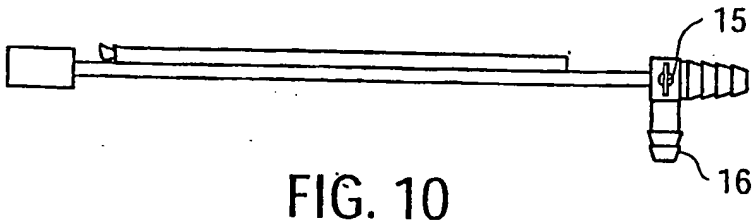


FIG. 10

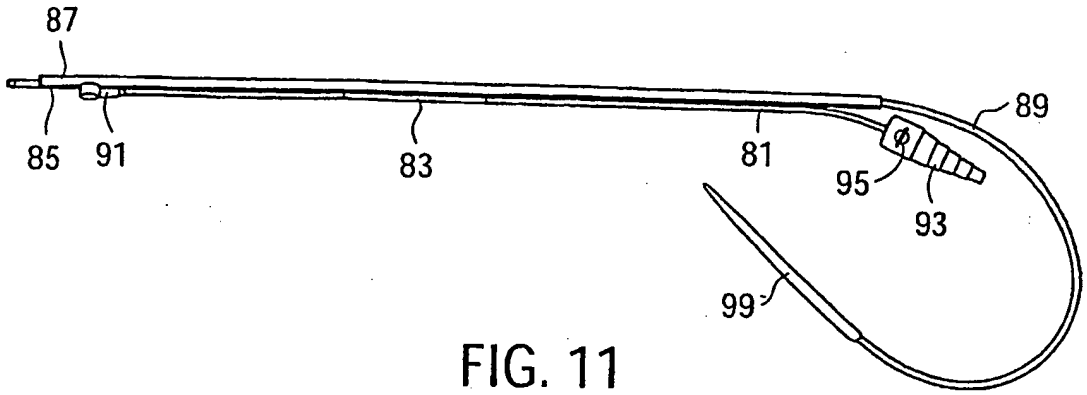


FIG. 11

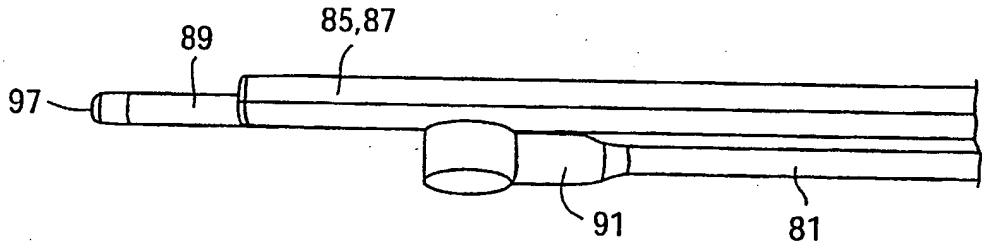


FIG. 12

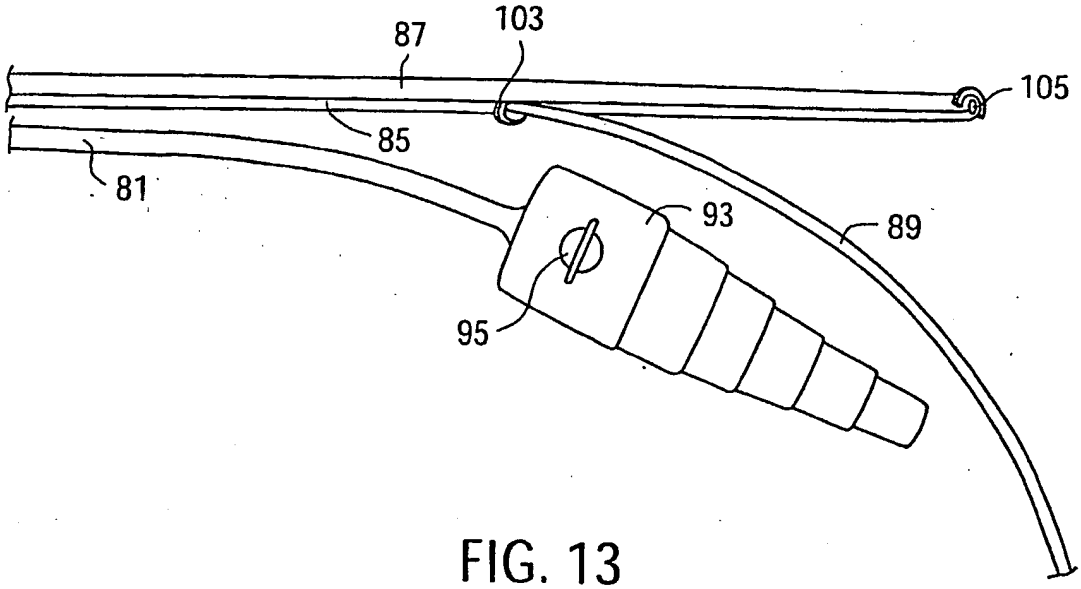


FIG. 13

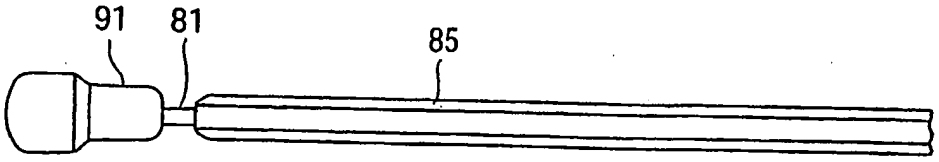


FIG. 14

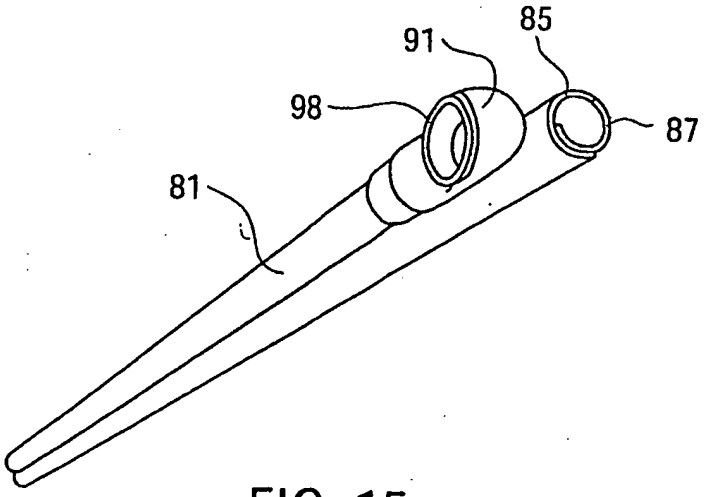


FIG. 15

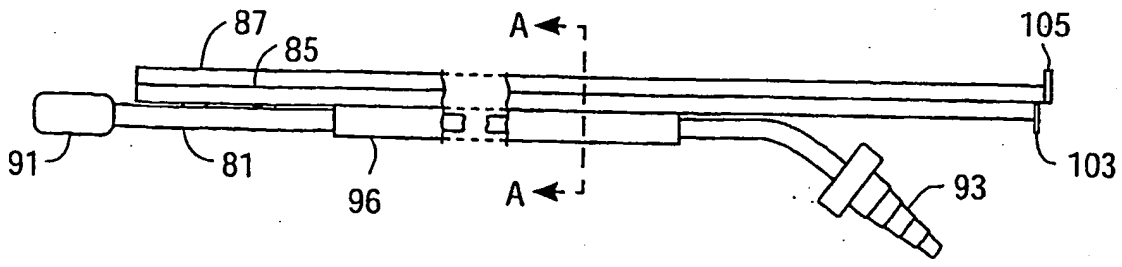


FIG. 16

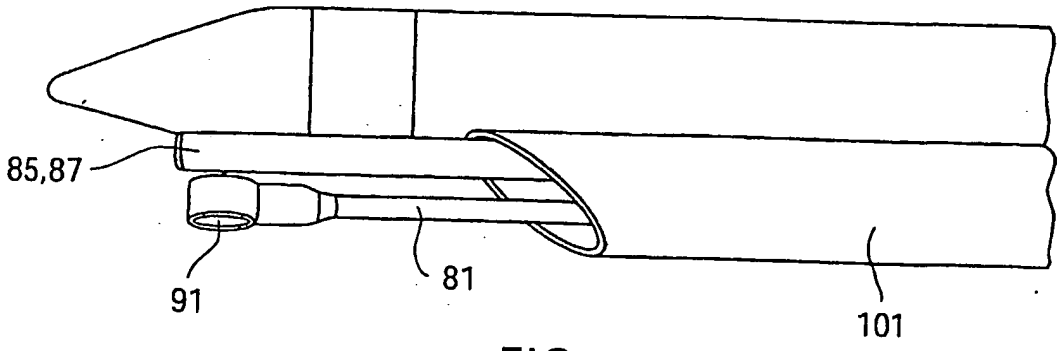


FIG. 17

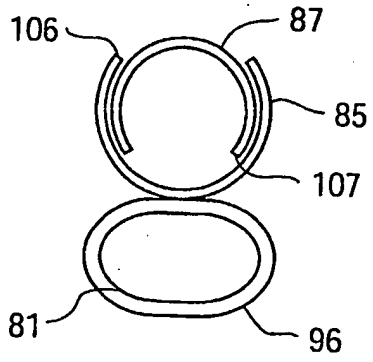


FIG. 18

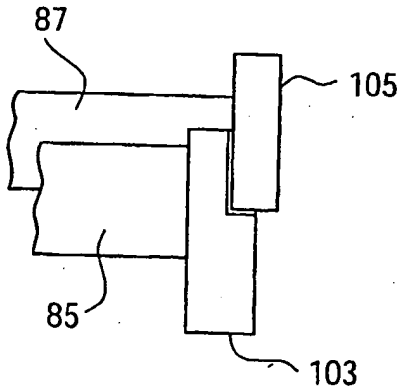


FIG. 19

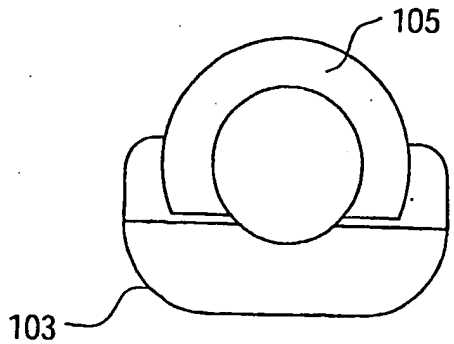


FIG. 20

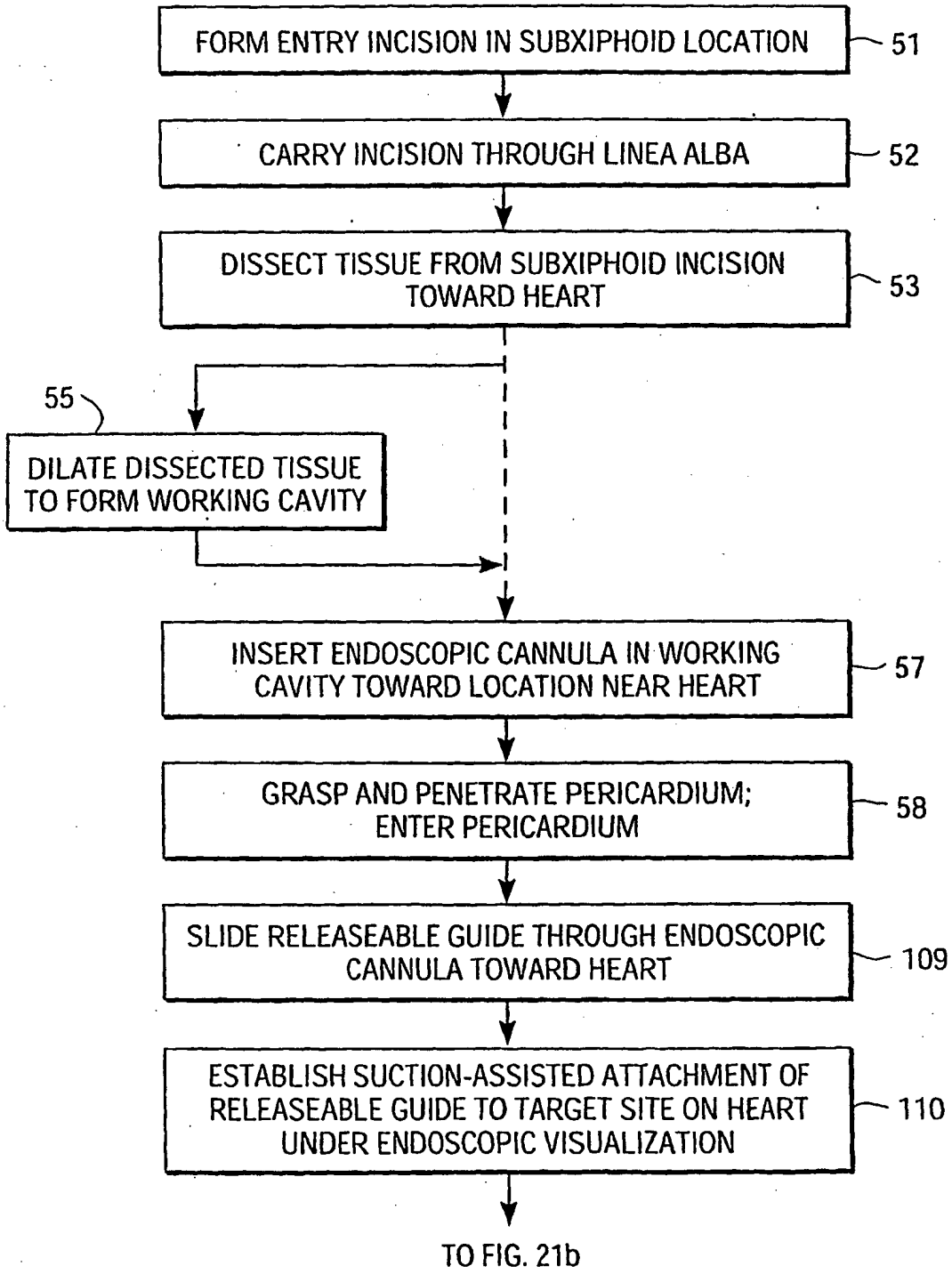

FORM ENTRY INCISION IN SUBXIPHOID LOCATION
51
CARRY INCISION THROUGH LINEA ALBA
52
DISSECT TISSUE FROM SUBXIPHOID INCISION TOWARD HEART
53
55
DILATE DISSECTED TISSUE TO FORM WORKING CAVITY
INSERT ENDOSCOPIC CANNULA IN WORKING CAVITY TOWARD LOCATION NEAR HEART
57
GRASP AND PENETRATE PERICARDIUM; ENTER PERICARDIUM
58
SLIDE RELEASEABLE GUIDE THROUGH ENDOSCOPIC CANNULA TOWARD HEART
109
ESTABLISH SUCTION-ASSISTED ATTACHMENT OF RELEASEABLE GUIDE TO TARGET SITE ON HEART UNDER ENDOSCOPIC VISUALIZATION
110
TO FIG. 21b

FIG. 21a

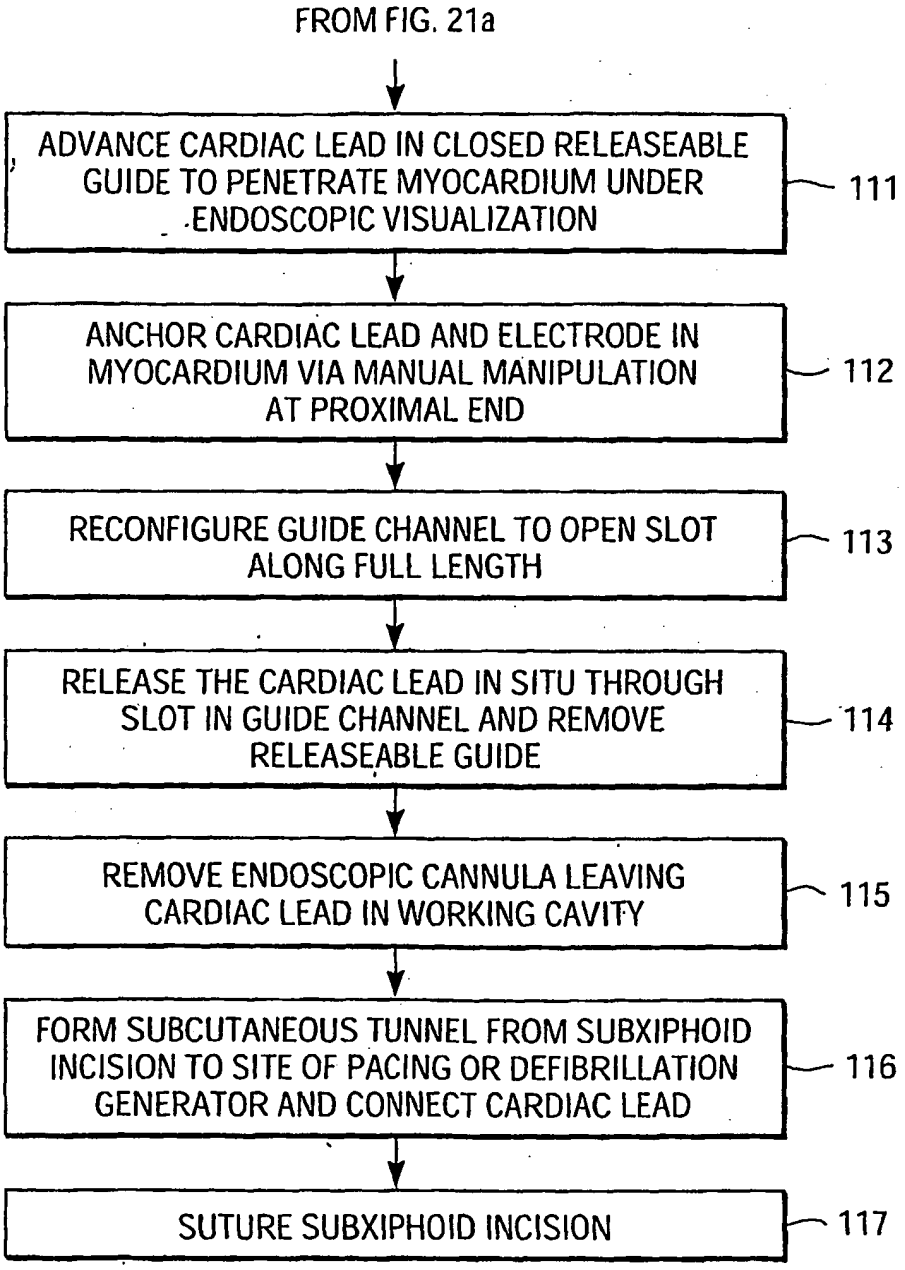

FROM FIG. 21a
ADVANCE CARDIAC LEAD IN CLOSED RELEASEABLE GUIDE TO PENETRATE MYOCARDIUM UNDER ENDOSCOPIC VISUALIZATION
111
ANCHOR CARDIAC LEAD AND ELECTRODE IN MYOCARDIUM VIA MANUAL MANIPULATION AT PROXIMAL END
112
RECONFIGURE GUIDE CHANNEL TO OPEN SLOT ALONG FULL LENGTH
113
RELEASE THE CARDIAC LEAD IN SITU THROUGH SLOT IN GUIDE CHANNEL AND REMOVE RELEASEABLE GUIDE
114
REMOVE ENDOSCOPIC CANNULA LEAVING CARDIAC LEAD IN WORKING CAVITY
115
FORM SUBCUTANEOUS TUNNEL FROM SUBXIPHOID INCISION TO SITE OF PACING OR DEFIBRILLATION GENERATOR AND CONNECT CARDIAC LEAD
116
SUTURE SUBXIPHOID INCISION
117

FIG. 21b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/18238

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/32; 19/00
US CL : 606/170, 129

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/170, 129, 167, 172, 179

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,336,252 A (COHEN) 09 August 1994, (09.08.1994), see entire document.	1-4, 17, 18, --- 5, 6, 9, 10, 11, 12, 13, 15, 16
Y	US 5,902,331 A (BONNER et al.) 11 May 1999 (11.05.1999), see FIG. 5-8 and Column 15 line 51-Column 17 line 8.	5, 6, 9, 10, 11, 12, 13, 15, 16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 August 2003 (21.08.2003)	28 OCT 2003
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Jessica R Baxter Telephone No. 703-308-0858

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